

EXHIBIT E

Karen A. Frank, M.D.

Videotaped

June 30, 2010

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: DIGITEK PRODUCT
LIABILITY LITIGATION

MDL NO. 1968

Videotaped deposition of KAREN A. FRANK, M.D., taken at the law offices of SEGAL McCAMBRIDGE SINGER & MAHONEY, LTD., 1818 Market Street, Suite 2600, Philadelphia, Pennsylvania, on Wednesday, June 30, 2010, commencing at 9:10 a.m., before Dianna R. Pugliese, a Registered Merit Reporter, Certified Realtime Reporter, Certified Shorthand Reporter (NJ & DE), and Notary Public, pursuant to notice.

Karen A. Frank, M.D.

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<p>1 APPEARANCES 2 FOR THE PLAINTIFF: 3 Mr. Fred Thompson, III 4 Motley Rice LLC 5 28 Bridgeside Boulevard 6 Mount Pleasant, South Carolina 29464 7 843-216-9118 8 9 FOR THE DEFENDANTS: 10 Mr. Richard A. Dean 11 Tucker Ellis & West LLP 12 1150 Huntington Building 13 925 Euclid Avenue 14 Cleveland, Ohio 44115-1475 15 216-696-2137 16 17 Ms. Monee A. Takla 18 Tucker Ellis & West LLP 19 515 South Flower Street, 42nd Floor 20 Los Angeles, California 90071 21 213-430-3378 22 23 Mr. Harvey L. Kaplan 24 Shook, Hardy & Bacon, LLP 25 255 Grand Boulevard Kansas City, Missouri 64108 816-474-6550 ALSO PRESENT: David Williams, Video Operator EXAMINATION INDEX KAREN A. FRANK, M.D. BY MR. DEAN 5 BY MR. KAPLAN 247 BY MR. THOMPSON 268 BY MR. KAPLAN 286 BY MR. DEAN 297 BY MR. KAPLAN 302</p>	<p>1 COURT REPORTER: Are there any 2 stipulations for the record? 3 MR. DEAN: No. 4 VIDEO OPERATOR: We're now on the video 5 record. 6 This is the videotape deposition of 7 Karen A. Frank, M.D., taken by the Defendant, In Re: 8 Digitek Product Liability Litigation, in the United 9 States District Court for the Southern District of 10 West Virginia, Charleston Division, held at the 11 offices of Segal McCambridge Singer & Mahoney, Ltd., 12 1818 Market Street, Philadelphia, Pennsylvania, on 13 Wednesday, June 30, 2010. 14 The time is 9:10 a.m. 15 I am David Williams, the videographer. 16 The court reporter is Dianna Pugliese. We are from 17 the firm of Rennillo Court Reporting in Cleveland, 18 Ohio. 19 Counsel, will you now please introduce 20 yourselves. 21 MR. DEAN: My name is Richard Dean. I 22 represent the Actavis defendants. 23 MS. TAKLA: Monee Takla for the Actavis 24 defendants. 25 MR. KAPLAN: Harvey Kaplan, Shook, Hardy</p>
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<p>1 EXHIBIT INDEX 2 MARKED 3 D 4 250 Digitek Expert Table of Contents with 45 5 18 items listed 6 251 Table of Contents with 11 items 45 7 listed 8 252 Handwritten notes by Dr. Frank, four 47 9 pages 10 253 Handwritten notes by Dr. Frank, 24 47 11 pages 12 254 Handwritten notes by Dr. Frank, one 47 13 page 14 255 Index titled Documents Sent to Karen 53 15 Frank, two pages 16 256 Handwritten notes of Karen Frank, one 55 17 page 18 257 Engagement Agreement with Smart 58 19 Consulting Group, LLC, six pages 20 258 Digitek Case Overview, 11 pages 59 21 259 Handwritten notes by Dr. Frank, one 60 22 page 23 260 Handwritten notes by Dr. Frank, one 60 24 page 25 261 Color photocopy of Dr. Frank's report 69 titled Digitek Recall, Assessment of Pharmacovigilance Systems and Risk Communication, Background, Analysis and Conclusions, 6/15/2010</p>	<p>1 & Bacon, for Mylan. 2 MR. THOMPSON: Fred Thompson, Motley 3 Rice, for Plaintiffs. 4 VIDEO OPERATOR: The reporter will now 5 swear in the witness. 6 KAREN A. FRANK, M.D., having been duly 7 sworn, was examined and testified as follows: 8 EXAMINATION 9 BY MR. DEAN: 10 Q. Good morning. 11 A. Good morning. 12 Q. Would you state your full name for the 13 record, please? 14 A. Karen Ann Frank. 15 Q. And it's Dr. Frank; correct? 16 A. Yes. 17 Q. Dr. Frank, we met before, but my name is 18 Richard Dean. 19 Have you ever had your deposition taken 20 before? 21 A. No. 22 Q. So this is your very first deposition 23 ever; correct? 24 A. Yes. 25 Q. Have you ever testified in a court in</p>

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<p>1 front of a jury before?</p> <p>2 A. No.</p> <p>3 Q. Has Mr. Thompson or someone else on</p> <p>4 behalf of the plaintiffs had a chance to tell you</p> <p>5 about the deposition process a little bit?</p> <p>6 A. Yes.</p> <p>7 Q. Okay. Well, let me just go over a few</p> <p>8 ground rules.</p> <p>9 I'm going to be asking you some</p> <p>10 questions today, so it's very important that the two</p> <p>11 of us communicate. So if I ask you a question that</p> <p>12 you do not understand, will you tell me that?</p> <p>13 A. Yes.</p> <p>14 Q. Your responses have to be verbal, out</p> <p>15 loud. We can't -- this court reporter, at least,</p> <p>16 can't take the shaking or nodding of the head in a</p> <p>17 particular direction.</p> <p>18 So will you speak up and use whatever</p> <p>19 words you want to use, but please speak up and give</p> <p>20 your answer verbally?</p> <p>21 A. Yes.</p> <p>22 Q. And I understand you're not -- you're a</p> <p>23 little bit under the weather today?</p> <p>24 A. Yes.</p> <p>25 Q. At any point if you need a break for any</p>	<p>1 not to write the report, but to get ready for the</p> <p>2 deposition.</p> <p>3 What is it that you did to get ready for</p> <p>4 the deposition today?</p> <p>5 A. I reread these two documents yesterday.</p> <p>6 Q. And by these two documents, for the</p> <p>7 record, you are referring to what I've marked already</p> <p>8 as Defendant's Exhibits 49 and 50; is that correct?</p> <p>9 A. Yes. I went back and reviewed to</p> <p>10 refresh my memory.</p> <p>11 Q. Well, actually, 40 -- just so we're</p> <p>12 clear, 49 is a copy of your resume; correct?</p> <p>13 A. No.</p> <p>14 Q. No?</p> <p>15 A. This -- what I reviewed was a copy of</p> <p>16 the Conclusion.</p> <p>17 Q. Right.</p> <p>18 A. And I went through this document. I</p> <p>19 can't say that I went through it a hundred percent. I</p> <p>20 went through key sections where I wanted to refresh my</p> <p>21 memory.</p> <p>22 Q. And for the record, what you have is the</p> <p>23 long document we've marked as Exhibit 50 to this</p> <p>24 deposition; is that correct?</p> <p>25 A. Yes.</p>
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<p>1 reason, just let us know and we'll take a break.</p> <p>2 Okay.</p> <p>3 A. Uh-huh.</p> <p>4 Q. Yes?</p> <p>5 A. Yes.</p> <p>6 Q. What have you done to prepare for the</p> <p>7 deposition today?</p> <p>8 A. I was sent a set of volumes of printed</p> <p>9 material. I went through them generally, and then I</p> <p>10 went through them looking for white space or blanks</p> <p>11 with information that I thought should be there that</p> <p>12 was not there.</p> <p>13 I met with Pete Miller and Megan Carter</p> <p>14 over lunch, and I presented them with a list of</p> <p>15 documents that I would liked to have seen, and they</p> <p>16 referenced it against what was available in discovery</p> <p>17 and they sent me two more printed volumes, electronic</p> <p>18 copies of everything I had electronic copies of.</p> <p>19 And then one final Establishment</p> <p>20 Inspection Report.</p> <p>21 MR. KAPLAN: One final what?</p> <p>22 THE WITNESS: Establishment Inspection</p> <p>23 Report.</p> <p>24 BY MR. DEAN:</p> <p>25 Q. My question was, what you did to get --</p>	<p>1 Q. And I compared them before. Your</p> <p>2 document has 70 pages and Exhibit 50 also has 70</p> <p>3 pages, so they are the same.</p> <p>4 A. There should be no alterations between</p> <p>5 what you received and what I printed.</p> <p>6 Q. So what you did in preparation for the</p> <p>7 deposition was to review what we marked as Exhibit 50;</p> <p>8 correct?</p> <p>9 A. I don't know why this is not marked as</p> <p>10 an exhibit, because this is the key opinion. This was</p> <p>11 at one point one document. And at the request of Pete</p> <p>12 Miller, it was split. So he asked me to address two</p> <p>13 separate issues --</p> <p>14 Q. Let me just interrupt. I won't do that</p> <p>15 often, but I want to make sure we get this exhibit</p> <p>16 marked correctly.</p> <p>17 The shorter document that you have in</p> <p>18 front of you is -- are you telling me that's not</p> <p>19 included in Exhibit 50?</p> <p>20 A. Yes. It is not included in Exhibit 50.</p> <p>21 Q. Okay. Can I see it, please?</p> <p>22 A. Yes. (Document provided.)</p> <p>23 Q. Dr. Frank, I have just reviewed the</p> <p>24 first 11 pages of Exhibit 50 and it -- it would --</p> <p>25 those first set of pages would appear to be exactly</p>

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<p>1 what is in the shorter document.</p> <p>2 A. Okay.</p> <p>3 Q. Is there a difference?</p> <p>4 A. Well, these were sent to Pete Miller as</p> <p>5 two separate documents. It may be that he combined</p> <p>6 it. He asked me to separate them. I actually started</p> <p>7 with an assessment of the pharmacovigilance system, an</p> <p>8 assessment of the risk communication.</p> <p>9 He asked me to combine them all, the</p> <p>10 opinions, as a conclusion.</p> <p>11 Then he said, this is too long. We want</p> <p>12 to take out this supporting document where I</p> <p>13 documented verbatim things from the FDA inspections</p> <p>14 and my comments that served as the basis for the</p> <p>15 opinion.</p> <p>16 And this short document became the</p> <p>17 opinion and this longer document became the supporting</p> <p>18 evidence.</p> <p>19 He may have, in the process of</p> <p>20 submitting it electronically, been forced to recombine</p> <p>21 them so that they were in this order.</p> <p>22 Q. Just so we're -- just so the record is</p> <p>23 clear --</p> <p>24 MR. THOMPSON: Yeah. Let's --</p> <p>25 BY MR. DEAN:</p>	<p>1 there is the one combined document and then the two</p> <p>2 separate documents that were sent to Pete Miller by</p> <p>3 e-mail.</p> <p>4 And there are copies, exact copies of</p> <p>5 this flash drive, two made, if you need to verify</p> <p>6 that.</p> <p>7 BY MR. DEAN:</p> <p>8 Q. So I want to get back to what you did to</p> <p>9 prepare for the deposition besides read -- read what</p> <p>10 we've marked as Exhibit 50, or the first 11 pages of</p> <p>11 Exhibit 50.</p> <p>12 A. Well, actually, it was -- it was the</p> <p>13 great deal of this. I didn't read all the verbatim</p> <p>14 quotes. I went mostly through my comments in this</p> <p>15 document. But, no, I did not go back to the original</p> <p>16 binders yesterday.</p> <p>17 Q. Okay.</p> <p>18 A. I only went through the original binders</p> <p>19 to extrapolate this, because I anticipated that this</p> <p>20 would ground my statements very carefully. The --</p> <p>21 what actually happened over the course of several</p> <p>22 years at this company is somewhat complex.</p> <p>23 And in the course of preparing this</p> <p>24 document, I laid out a timeline of events and the</p> <p>25 observations of the inspectors.</p>
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<p>1 Q. Could you look at -- could you,</p> <p>2 yourself --</p> <p>3 MR. THOMPSON: Yeah, could I -- let me</p> <p>4 just make a short statement, and that is, everything</p> <p>5 Dr. Frank has said is true and accurate.</p> <p>6 Everything you said is true and</p> <p>7 accurate. That she submitted a -- the lengthy</p> <p>8 document.</p> <p>9 We determined and we believe that for</p> <p>10 the ease of having a report and a supplement, that the</p> <p>11 thing to do would be to have it as a separate with a</p> <p>12 supplement.</p> <p>13 But in terms of the report, the</p> <p>14 connection or disconnection is irrelevant.</p> <p>15 And so what you have, I believe, is what</p> <p>16 Dr. Frank has as the report with, immediately</p> <p>17 following it, this lengthy discussion item by item as</p> <p>18 sort of a supplement or a supporting information.</p> <p>19 So I think that it's tempest in a</p> <p>20 teapot. In Dr. Frank's mind, she separated them. In</p> <p>21 submission, they were submitted --</p> <p>22 MR. DEAN: Together.</p> <p>23 MR. THOMPSON: -- as a report with</p> <p>24 supplement, so...</p> <p>25 THE WITNESS: Electronically on this</p>	<p>1 Because most of what I was presented was</p> <p>2 the 483s and the Establishment Inspection Reports were</p> <p>3 the paucity of what you might call primary.</p> <p>4 MR. THOMPSON: Doctor, let me do some</p> <p>5 impermissible coaching, and that is, if I thought that</p> <p>6 it would shorten the deposition, I would let you go</p> <p>7 forward with those explanations.</p> <p>8 But I'm afraid that we're going to get</p> <p>9 back to that --</p> <p>10 MR. DEAN: Right.</p> <p>11 MR. THOMPSON: -- over the course of the</p> <p>12 day.</p> <p>13 THE WITNESS: Okay.</p> <p>14 MR. THOMPSON: Right now, I think what</p> <p>15 he wants to know is simply what was done to prepare</p> <p>16 for this deposition, and he probably wants to know</p> <p>17 about our meeting last night and our meeting this</p> <p>18 morning.</p> <p>19 THE WITNESS: Okay.</p> <p>20 MR. THOMPSON: And the review of the</p> <p>21 exhibit from the deposition, and I don't recall the</p> <p>22 exhibit number, but it was the FDA document, the fact</p> <p>23 sheet.</p> <p>24 And I think that once we say that, that</p> <p>25 will be exhaustive.</p>

4 (Pages 10 to 13)

<p style="text-align: right;">Page 14</p> <p>1 THE WITNESS: Okay. I'm sorry.</p> <p>2 MR. DEAN: Thank you, Mr. Thompson.</p> <p>3 BY MR. DEAN:</p> <p>4 Q. Go ahead.</p> <p>5 A. Do I give him the details of the meeting</p> <p>6 last night?</p> <p>7 Q. Well, let's just do it this way. Let me</p> <p>8 ask a question, I'll try to have a focused question,</p> <p>9 you give a focused answer.</p> <p>10 Mr. Thompson is right, we'll get back to</p> <p>11 the substance of your opinions much later -- or later</p> <p>12 this morning. But for right now, let's just -- I'll</p> <p>13 give you a very short question, you try to give me a</p> <p>14 direct answer to the question. Okay?</p> <p>15 A. Okay.</p> <p>16 Q. So I take it, in the last few days, you</p> <p>17 have met with Mr. Thompson; is that correct?</p> <p>18 A. Yes.</p> <p>19 Q. Did you meet with any other attorneys</p> <p>20 for the plaintiffs in the last few days?</p> <p>21 A. On the phone were Megan Carter and Pete</p> <p>22 Miller.</p> <p>23 Q. And when did -- and was Mr. Thompson on</p> <p>24 that call?</p> <p>25 A. Yes. He was chairing the call.</p>	<p style="text-align: right;">Page 16</p> <p>1 documents that I was not sent, that -- there was</p> <p>2 suggestion that I review them last night or sometime</p> <p>3 in the future to further expand the analysis.</p> <p>4 There was discussion of some general FDA</p> <p>5 press releases on generic drugs and their implications</p> <p>6 that they may be presented to me today.</p> <p>7 And there was -- there was just some</p> <p>8 general coaching in how to give appropriate opinions.</p> <p>9 And I believe they were very, very careful to stay</p> <p>10 within bounds with coaching the witness.</p> <p>11 My only other presentations such as this</p> <p>12 are before FDA advisory committees, which are largely</p> <p>13 data driven. They were internal, closed-door</p> <p>14 presentations. And they were very carefully reviewed</p> <p>15 up front. So --</p> <p>16 Q. Excuse me. I missed that. They were</p> <p>17 very carefully what --</p> <p>18 A. Reviewed up front with FDA supervisors.</p> <p>19 Q. Okay.</p> <p>20 A. So this is the first time I've sat at</p> <p>21 deposition. I will make a statement that I've been</p> <p>22 approached about doing this work previously, maybe</p> <p>23 eight years ago. People recommended --</p> <p>24 MR. THOMPSON: Dr. Frank, let me ask you</p> <p>25 to be responsive to Mr. Dean.</p>
<p style="text-align: right;">Page 15</p> <p>1 Q. And when was that?</p> <p>2 A. That was last evening.</p> <p>3 Q. Was that -- within the last week, was</p> <p>4 that the first time you met with any attorney</p> <p>5 representing the plaintiffs?</p> <p>6 A. Yes.</p> <p>7 Q. How long did that call last?</p> <p>8 A. Approximately two hours. It was</p> <p>9 intermittent. It was interrupted. It was scheduled</p> <p>10 to last from 5:30 to 7:30.</p> <p>11 I was down in the lobby at 6:30</p> <p>12 expecting Mr. Miller to meet me, and at quarter of</p> <p>13 6:00 I called him on his phone and he had expected me</p> <p>14 to call him when I arrived. So we started late and I</p> <p>15 believe we went about 15 minutes late.</p> <p>16 Q. What subjects did you discuss?</p> <p>17 A. I discussed some general opinions that I</p> <p>18 had about the situation and some specific issues that</p> <p>19 came from the evidence here. They presented me with</p> <p>20 the issues that had come up in the depositions.</p> <p>21 And we talked about how I would stick to</p> <p>22 the scope of my engagement, how I would respond if the</p> <p>23 questioning started to go outside of the scope of my</p> <p>24 engagement.</p> <p>25 They made me aware of some additional</p>	<p style="text-align: right;">Page 17</p> <p>1 THE WITNESS: Okay.</p> <p>2 MR. THOMPSON: I think he has now</p> <p>3 exhausted the -- maybe he hasn't exhausted, but we're</p> <p>4 on the preparation for this deposition.</p> <p>5 THE WITNESS: Okay.</p> <p>6 BY MR. DEAN:</p> <p>7 Q. All right. Thank you for that answer,</p> <p>8 which I think was responsive, but I want to go back</p> <p>9 and ask you some follow-ups on specific things that</p> <p>10 you said in that answer.</p> <p>11 You said, first of all, that they --</p> <p>12 "they" being the lawyers -- presented you with issues</p> <p>13 that had come up in the depositions, by that I mean --</p> <p>14 I'm assuming you meant depositions that have occurred</p> <p>15 in the last few days?</p> <p>16 A. Yes.</p> <p>17 Q. What issues did they present you with?</p> <p>18 A. The one that really struck me was the</p> <p>19 fact that the -- there was a repeated line of</p> <p>20 questioning about specific information on Digitek.</p> <p>21 And I responded to them that if you were</p> <p>22 to look at the volumes that I reviewed several weeks</p> <p>23 ago to write this document, you will see in my notes</p> <p>24 in the margin, Digitek question, Digitek question.</p> <p>25 Because there's not a lot of specific</p>

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1 information given on the systems that allow specific
 2 analysis of the subset of data on Digitek.
 3 And so I understood why your line of
 4 questioning went in that direction, and we prepared me
 5 to answer. And I think I can -- I've produced a
 6 document that can -- is an accurate basis for any
 7 answer to that.
 8 Q. I don't -- I want to follow up. You
 9 said they presented you with the issue that there was
 10 not much specific information on Digitek.
 11 Could you be more specific about what
 12 the issue was they were talking to you about?
 13 A. They didn't state that there was no
 14 specific issue on Digitek. They said that your line
 15 of questioning repeatedly was to ask the witnesses do
 16 you have anything specific on Digitek.
 17 My extrapolation was my reaction to what
 18 I was given is that I was unable to subset out
 19 information on the systems specifically for Digitek.
 20 So when the FDA looks at noncompliance
 21 with 15-day reporting, they have a sampling that
 22 includes Digitek cases and non-Digitek cases.
 23 I don't know how that extrapolates.
 24 Nobody presented me with data from the database that
 25 shows X Digitek cases over X years, the adverse event

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1 codes.
 2 So I can't say that the analysis of the
 3 databases or the systems was specific for Digitek. It
 4 was analysis of the Actavis systems that handled all
 5 of the products. Nothing was specific to Digitek.
 6 MR. THOMPSON: You know, let me just
 7 interrupt here. Certainly you have a right to ask
 8 questions and certainly Dr. Frank has shown that she's
 9 going to be meticulously responsive.
 10 But if we're going to go through all
 11 this again and you're going to ask the question that
 12 we told her that you were probably going to ask, I'm
 13 just not -- I just hate to sit through it twice.
 14 BY MR. DEAN:
 15 Q. What other issues did they present you
 16 with besides the one you just spoke to us about?
 17 A. I'm having trouble recalling
 18 specifically. We talked a lot about my staying within
 19 the scope of my engagement because --
 20 Q. I don't need to go there. I understand
 21 that.
 22 I just want to know, I'm interested in
 23 what issues they flagged for you last night. You've
 24 told me about one issue.
 25 Are there any others they flagged for

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1 you?
 2 A. I need to -- I wrote notes, but I don't
 3 think I have written them all down, and I don't --
 4 Q. Did you make notes at that meeting,
 5 ma'am?
 6 A. Nothing -- only my to-do list for last
 7 night.
 8 MR. KAPLAN: Can we get a copy of that?
 9 MR. DEAN: Well, let me look at it
 10 first. I'm not sure we want it.
 11 MR. THOMPSON: Why don't you look at it
 12 before you say that.
 13 BY MR. DEAN:
 14 Q. For Mr. Kaplan's benefit, could you just
 15 read what's on here so -- I don't think we're going to
 16 need a copy of that.
 17 A. It says, Two flash drives, check
 18 e-mail. And I don't know -- I don't know what the
 19 other one says.
 20 What I wanted to make sure is that I had
 21 all of the required evidence that you wanted for the
 22 deposition.
 23 Q. Now, let's -- thank you.
 24 Now, I want to make sure you've answered
 25 my question, though. I just want a listing of the

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1 issues they presented to you. You've given me one
 2 issue.
 3 Are there any other issues?
 4 A. They talked to me about how to respond
 5 to questions that had multiple questions in one
 6 question, to ask for it to be subdivided. They --
 7 Q. Excuse me. I'm not interested in their
 8 instructions about how to respond to questions.
 9 What I'm interested in are simply this.
 10 Are there substantive issues at the beginning of the
 11 meeting that they flagged for you as issues that might
 12 come up in the deposition? That's all I want to know.
 13 A. At the moment, I can't remember any
 14 more.
 15 Q. Okay. Thank you.
 16 Now --
 17 A. I think -- I'm sorry I'm so nervous, but
 18 I'm -- actually, I can't remember the specifics.
 19 Q. You'll get more -- I know at the
 20 beginning this is -- you're going to be nervous.
 21 You'll get comfortable.
 22 And if you think of those issues later,
 23 if they come back to you, we'll give you an
 24 opportunity.
 25 A. Yes.

6 (Pages 18 to 21)

Karen A. Frank, M.D.

Videotaped

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<p>1 MR. THOMPSON: I hate to -- I hate to</p> <p>2 interrupt again, but I do believe Dr. Frank did</p> <p>3 mention that we read to her the FDA Generic Drug</p> <p>4 Advisory.</p> <p>5 MR. DEAN: I've got the list here.</p> <p>6 MR. THOMPSON: Okay.</p> <p>7 MR. DEAN: I'm getting there.</p> <p>8 MR. THOMPSON: Okay.</p> <p>9 BY MR. DEAN:</p> <p>10 Q. The next thing you mentioned when you</p> <p>11 were giving me the list of what happened last night</p> <p>12 was that they gave you additional documents that had</p> <p>13 not been sent to you.</p> <p>14 What documents did they give to you that</p> <p>15 had not been sent?</p> <p>16 A. They were unable to access the server.</p> <p>17 The only way to obtain some of the documents was</p> <p>18 through the Citrix portal on his laptop, and that was</p> <p>19 not functioning. They were unable to download the</p> <p>20 documents and send them to me by e-mail.</p> <p>21 Your line of questioning along specific</p> <p>22 issues for Digitek brought up issues that were already</p> <p>23 of concern to me.</p> <p>24 So a lot of what happened last night</p> <p>25 was, I expressed my concerns and they responded to</p>	<p>1 Q. Okay. And did you look at any</p> <p>2 additional documents this morning?</p> <p>3 A. I read these this morning.</p> <p>4 Q. Read what this morning?</p> <p>5 Oh, no. I meant -- I meant additional</p> <p>6 -- additional evidentiary documents, exhibits.</p> <p>7 A. No.</p> <p>8 Q. Okay. So the only additional document</p> <p>9 that you looked at in the last two days was that --</p> <p>10 what you referred to as a generic press release; is</p> <p>11 that correct?</p> <p>12 A. Yes. Now --</p> <p>13 Q. Is that correct?</p> <p>14 A. Yes. You --</p> <p>15 Q. You've answered. Okay? It was a very</p> <p>16 simple question.</p> <p>17 Let's -- let me go on and frame another</p> <p>18 one for you.</p> <p>19 A. Okay.</p> <p>20 Q. I believe in your original answer to me</p> <p>21 you mentioned that you discussed some FDA statements.</p> <p>22 Was that just the generic statement we</p> <p>23 just spoke about?</p> <p>24 A. Yes.</p> <p>25 Q. Yes?</p>
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<p>1 prepare me to address my concerns this morning.</p> <p>2 And in coaching me to stay within the</p> <p>3 scope of my work, there were a number of documents</p> <p>4 that were not sent to me, but were sent to the other</p> <p>5 witnesses, the cardiologist who looked at the medical</p> <p>6 issues.</p> <p>7 Even though I'm a medical doctor, I was</p> <p>8 not sent a lot of these.</p> <p>9 So we talked about that. We talked</p> <p>10 about my concerns with the process of discovery in</p> <p>11 this case.</p> <p>12 Q. Now, let me just stop you. You've gone</p> <p>13 beyond my question. I'm going to give you a chance to</p> <p>14 tell me whatever you want to tell me, but I'd like to</p> <p>15 do it in a question-and-answer fashion.</p> <p>16 Did you look at any additional documents</p> <p>17 last night or were you foiled by technology from being</p> <p>18 able to look at additional documents?</p> <p>19 A. We were foiled by technology, except for</p> <p>20 one document.</p> <p>21 Q. And what is that, ma'am?</p> <p>22 A. Which is a generic press release by the</p> <p>23 FDA talking about the generics industry where they</p> <p>24 read to me specific points and warned me that it may</p> <p>25 be presented to me today.</p>	<p>1 A. I didn't see anything else in writing.</p> <p>2 Q. Now, about three minutes ago you said</p> <p>3 that this morning you expressed your concerns about</p> <p>4 some issues.</p> <p>5 A. Well, last night and this morning.</p> <p>6 Q. Okay. And what concerns did you express</p> <p>7 about issues?</p> <p>8 A. Well, I wanted to be certain that I</p> <p>9 didn't violate any of my existing confidentiality</p> <p>10 agreements.</p> <p>11 A lot of the background I draw from has</p> <p>12 to do with -- has to do with issues that I addressed</p> <p>13 in pharma companies or where I had been provided</p> <p>14 information from my FDA mentors about drug</p> <p>15 withdrawals.</p> <p>16 I know a lot about the investigations</p> <p>17 that went on in some of these and they coached me how</p> <p>18 to comment on this evidence without bringing in</p> <p>19 evidence from other cases that would not be</p> <p>20 appropriate for this deposition.</p> <p>21 I expressed my other concern that when I</p> <p>22 was given these documents, I went through them, I then</p> <p>23 made a list of documents that I would like to have</p> <p>24 seen to completely analyze what happened in the</p> <p>25 company, and I presented to Pete Miller, and they were</p>

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1 concerned that the process of discovery was complete
2 and those documents were not available.

3 I did not go back and do the subsequent
4 gap analysis when they sent me the second round of
5 documents.

6 But in this document I prepared for
7 myself for this morning, I tried to clearly lay out
8 what I -- what was provided to me very accurately, and
9 things that were not provided to me, like any of the
10 MHRA inspections or the responses.

11 So my view inside Actavis, from 1992,
12 from the first consent decree, to now, is mostly
13 through the eyes of the FDA inspectors and their
14 observations.

15 And my opinions can only be based on
16 what I actually saw or read. These are secondary
17 sources.

18 I haven't seen the primary sources. I
19 haven't seen any individual MedWatch forms. I haven't
20 seen any PSURs.

21 I have not seen the company internal
22 document that was provided to Dr. Leikin at the time
23 of his Health Hazard Assessment. I have not seen the
24 Quality System Improvement Plan. I have not seen any
25 CAPAs, any CAPA trackers.

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1 MR. KAPLAN: Any what?

2 THE WITNESS: CAPA trackers. When
3 companies have CAPAs, they usually track their
4 compliance with the CAPAs with some sort of a tool.
5 Some are more robust than others. Some can be as
6 simple as an Excel spreadsheet.

7 But if they have an inspection and
8 they're anticipating a repeat two-year inspection,
9 they're documenting their remediation program on the
10 original inspection and what are their vulnerabilities
11 for the repeat inspection.

12 If they're working with a consulting
13 firm on business processes, they usually provide this
14 information to the consulting firm for the business
15 analysts and the modelers to use in assisting them in
16 building more robust business processes and improving
17 their compliance.

18 MR. THOMPSON: Let me -- here again, let
19 me -- this is not even an objection, is if I thought
20 that this was actually covering this information for
21 the whole day, I would allow Dr. -- I would say go,
22 continue, Dr. Frank.

23 She's clearly trying her best to give
24 full and responsive answers, but I'm concerned that
25 we're going to just repeat this same material and

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1 we're going to hear it twice.

2 So it's my hope that we can -- it's my
3 hope that she'll tell you that we told her to tell the
4 truth at some point, but even if she doesn't --

5 MR. DEAN: She's left that out so far,
6 Fred.

7 MR. THOMPSON: Yeah. I think we've --
8 anyway...

9 BY MR. DEAN:

10 Q. For Mr. Thompson's sake, did
11 Mr. Thompson tell you to tell the truth today?

12 A. Yes.

13 Q. Good.

14 A. Do you think I'm not telling the truth?

15 MR. THOMPSON: No. That's a lawyer joke
16 between the two of us. I apologize.

17 THE WITNESS: I have a concern that the
18 complexity of this -- I've been involved with
19 companies that have had implosions like this, and in
20 trying to correct it inside the company, the
21 exhaustion that occurs in trying to sort out what
22 happened and what needs to be corrected, how to
23 correct it and document the correction can be
24 prohibitive.

25 And in trying to sort out what really

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1 happened here very, very accurately, I don't want to
2 come in and make general statements that sound like
3 opinions.

4 There's -- there's a lot of evidence
5 here as to what happened, what was not reported, what
6 the inspectors found, what the companies promised to
7 do, what they did do in the remediation.

8 But there's white space that I have not
9 seen. It's not -- it may or may not be in the process
10 of discovery. It may have been that in limiting the
11 scope of my opinion it was not provided to me, it was
12 provided to someone else.

13 BY MR. DEAN:

14 Q. Okay. Let me hand you what I have
15 marked as Exhibit 90.

16 MR. DEAN: Fred. Harvey.

17 BY MR. DEAN:

18 Q. Exhibit 90 is a Notice for this
19 deposition asking you to bring certain documents with
20 you.

21 Have you seen this before?

22 A. Yes. I went over this with them last
23 night.

24 Q. Okay. Let's go through it.
25 Item number one, we already have your

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<p>1 curriculum vitae.</p> <p>2 Item number two was correspondence</p> <p>3 between you and any attorney acting on behalf of the</p> <p>4 plaintiffs in the Digitek litigation.</p> <p>5 Did you bring that with you?</p> <p>6 A. I have everything. I asked specifically</p> <p>7 twice whether I was to print e-mails. I was told no.</p> <p>8 I do not have any e-mails corresponding to the case.</p> <p>9 I asked them not to send any documents</p> <p>10 by e-mail. Everything was sent by FedEx either in</p> <p>11 paper or electronic format.</p> <p>12 Q. And did you bring items responsive to</p> <p>13 number two with you today?</p> <p>14 A. Yes.</p> <p>15 Q. And could I see that, please.</p> <p>16 A. I believe that I did print some SOPs,</p> <p>17 but I did not make comments on them. So what I know</p> <p>18 about document retention, I didn't alter the paper</p> <p>19 copy, and there is an electronic copy. It's</p> <p>20 equivalent.</p> <p>21 So I don't think I have all of the SOPs</p> <p>22 that I printed, but I have the electronic equivalents</p> <p>23 and there were no marks made on these.</p> <p>24 Q. Dr. Frank, you have given me four</p> <p>25 notebooks, some loose pages of paper and two CDs;</p>	<p>1 Q. Excuse me. Which notebooks would it</p> <p>2 summarize, Dr. Frank?</p> <p>3 A. I think the first two that were sent to</p> <p>4 me.</p> <p>5 Q. So -- and which would those be?</p> <p>6 A. Okay. That would be that one there</p> <p>7 (indicating).</p> <p>8 Q. Okay.</p> <p>9 A. And I specifically did not take time to</p> <p>10 categorize this. I called them and said, I don't have</p> <p>11 all the documents electronically for which I want to</p> <p>12 write this document. But I did not take the time to</p> <p>13 verify those disks against the binders.</p> <p>14 Q. Did you --</p> <p>15 A. And there could be variation, is what</p> <p>16 I'm saying.</p> <p>17 Q. I want to move through this as quickly</p> <p>18 as we can.</p> <p>19 But what I'm interested in is what you</p> <p>20 were -- what you were provided and then what you asked</p> <p>21 for, is -- in follow-up, is all of that here in front</p> <p>22 of us now?</p> <p>23 A. Yes.</p> <p>24 Q. Is there anything that's responsive --</p> <p>25 strike that.</p>
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<p>1 correct?</p> <p>2 A. Yes.</p> <p>3 Q. What is on the CDs?</p> <p>4 A. As many of the documents in these</p> <p>5 notebooks and that stack as were available</p> <p>6 electronically.</p> <p>7 Q. Okay. So these, the CDs, would not</p> <p>8 comprise everything that's in hard copy here?</p> <p>9 A. No. And I went back and asked, and I</p> <p>10 don't think all of them were available</p> <p>11 electronically. There were some that were to be</p> <p>12 delivered.</p> <p>13 That -- see that sheet there? That is</p> <p>14 the listing of at least one of the CDs. And the</p> <p>15 checks, I don't recall having received electronically</p> <p>16 the two documents there.</p> <p>17 Q. Well, if I was interested -- I'm not</p> <p>18 interested in hauling all this paper with me, but --</p> <p>19 or having it marked as exhibits if I can avoid it.</p> <p>20 There's a document here that says</p> <p>21 Documents sent to Karen Frank; correct?</p> <p>22 A. Yes.</p> <p>23 Q. Does it -- does this summarize some of</p> <p>24 these notebooks?</p> <p>25 A. Yes. Now, what I did not do --</p>	<p>1 Is there anything else you brought with</p> <p>2 you today other than what we have on the table?</p> <p>3 A. No. The directions to the hotel last</p> <p>4 night and my Notice.</p> <p>5 Q. Those I don't need.</p> <p>6 A. And this you have in electronic format,</p> <p>7 all of this.</p> <p>8 MR. THOMPSON: Let me interrupt. She</p> <p>9 brought these two thumb drives, which are two copies</p> <p>10 of the same thing. Maybe she needs to summarize</p> <p>11 what's on the thumb drives.</p> <p>12 MR. DEAN: Yes. Thank you, Fred.</p> <p>13 BY MR. DEAN:</p> <p>14 Q. Could you do that, please?</p> <p>15 A. When I started the review, the</p> <p>16 consulting firm that I worked for had me talk to</p> <p>17 somebody else who was doing expert witness work. And</p> <p>18 he said that he did individual reports of every</p> <p>19 document he reviewed. So I started that.</p> <p>20 But you will not find a whole lot of</p> <p>21 comments expressed in those documents because I held</p> <p>22 back very carefully. So there weren't frivolous</p> <p>23 comments made. Become -- what I did was --</p> <p>24 Q. All I want to know is, what's on the</p> <p>25 thumb drives?</p>

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<p style="text-align: right;">Page 34</p> <p>1 A. Those draft documents are here.</p> <p>2 Then what I did is, I became concerned</p> <p>3 about the complexity of what had happened and the</p> <p>4 amount of white space, and I started putting my own</p> <p>5 document together that is as close as I can track to</p> <p>6 verbatim quotes from the FDA inspections and the</p> <p>7 documents that I received.</p> <p>8 And after I put that together, I started</p> <p>9 going back and making substantive comments on that.</p> <p>10 And from the substantive comments, I drew the</p> <p>11 conclusions.</p> <p>12 It was a step-wise process that involved</p> <p>13 stopping the individual reports on the individual</p> <p>14 documents.</p> <p>15 That became out of scope, unauthorized</p> <p>16 work, and it was rolled into one review document with</p> <p>17 substantive comments and the conclusion.</p> <p>18 Q. Let's go back to Exhibit 90, please.</p> <p>19 MR. THOMPSON: I think what she was</p> <p>20 saying was that the various draft iterations of the</p> <p>21 final document --</p> <p>22 THE WITNESS: Right.</p> <p>23 MR. THOMPSON: -- are contained on the</p> <p>24 thumb drive.</p> <p>25 Is that right?</p>	<p style="text-align: right;">Page 36</p> <p>1 correspondence and communication, were there -- are</p> <p>2 there letters in here?</p> <p>3 A. No.</p> <p>4 Q. So did you -- did you ever exchange</p> <p>5 letters with one of the plaintiffs' lawyers?</p> <p>6 A. I received cover letters for each of</p> <p>7 these binders that I did not retain.</p> <p>8 Q. So the cover letter would have -- it</p> <p>9 would have just had a listing of what was in the -- in</p> <p>10 the materials; is that right?</p> <p>11 A. It didn't even have a listing. It</p> <p>12 looked like their generic cover letter.</p> <p>13 Q. Enclosed please find?</p> <p>14 A. Yeah.</p> <p>15 Q. Okay. All right.</p> <p>16 A. And the other thing that may be missing</p> <p>17 is, when I -- when they -- they coached me through the</p> <p>18 preparation of a nice document for you. Not for a</p> <p>19 client that's in trouble that needs to remediate.</p> <p>20 So there may be a few phone calls where</p> <p>21 I had a pad in my hand and I scribbled notes to</p> <p>22 myself. They were translated into this. Those notes</p> <p>23 probably --</p> <p>24 Q. Translated into what, ma'am?</p> <p>25 A. The documents that they were part of.</p>
<p style="text-align: right;">Page 35</p> <p>1 THE WITNESS: Yes.</p> <p>2 MR. THOMPSON: Okay.</p> <p>3 THE WITNESS: This whole process,</p> <p>4 including the truncated short reports.</p> <p>5 MR. THOMPSON: Okay.</p> <p>6 THE WITNESS: Which you're welcome to</p> <p>7 review, which should not have -- they will have</p> <p>8 comments, they won't be substantive. They were very,</p> <p>9 very lightweight comments.</p> <p>10 The heavy comments were, for the most</p> <p>11 part, restricted to this document and very carefully</p> <p>12 tracked to the verbatim evidence.</p> <p>13 MR. THOMPSON: Okay.</p> <p>14 BY MR. DEAN:</p> <p>15 Q. What I'm -- thank you.</p> <p>16 What I'm trying to get at now -- and I</p> <p>17 appreciate your answer. What I'm trying to get at now</p> <p>18 is the documents that are called for in the -- in the</p> <p>19 Notice, which is Exhibit Number 90.</p> <p>20 And so all the correspondence and</p> <p>21 communications you would have would be in what we have</p> <p>22 in front of us right now; correct?</p> <p>23 Would be somewhere in here; correct?</p> <p>24 A. Yeah.</p> <p>25 Q. All right. Where, in terms of</p>	<p style="text-align: right;">Page 37</p> <p>1 Q. Would they -- if you took notes, would</p> <p>2 they be on a piece of paper that would be somewhere in</p> <p>3 the stack in front of us?</p> <p>4 A. Some of them are.</p> <p>5 Q. Okay.</p> <p>6 A. There may be -- there may be stray notes</p> <p>7 that were lost.</p> <p>8 Q. Would it be -- would it be fair for me</p> <p>9 to assume that if there are such notes, they would be</p> <p>10 in this stack of paper right here?</p> <p>11 A. Yes.</p> <p>12 Q. Could you -- could you --</p> <p>13 A. The -- the --</p> <p>14 Q. Well, hang on. I can make it even</p> <p>15 easier.</p> <p>16 Because Plaintiff's Exhibit 91 is in</p> <p>17 here; correct?</p> <p>18 A. Yes.</p> <p>19 Q. So --</p> <p>20 A. I can tell you what I think is missing.</p> <p>21 Q. Well, let's stay on -- let's stay on</p> <p>22 task here.</p> <p>23 A. Okay.</p> <p>24 Q. We're on number two. Is there -- in</p> <p>25 what you've brought with you today, is there any</p>

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<p>1 correspondence between you and the plaintiffs'</p> <p>2 lawyers?</p> <p>3 A. Nothing of substance.</p> <p>4 Q. Is there anything? In what we have</p> <p>5 here, is there any correspondence?</p> <p>6 A. No. They're only documents. The</p> <p>7 letters were all these generic cover letters.</p> <p>8 Q. All right. Fine.</p> <p>9 Then number three, it says, all other</p> <p>10 documents prepared by attorneys for the plaintiff and</p> <p>11 sent to the witness.</p> <p>12 Would they all be in front of us here?</p> <p>13 A. Can you repeat the question?</p> <p>14 Q. Yes. I'm on number three, Dr. Frank.</p> <p>15 We asked you to bring all other</p> <p>16 documents prepared by attorneys for the plaintiffs and</p> <p>17 sent to the witness.</p> <p>18 Would they all be in front of us?</p> <p>19 A. Yes.</p> <p>20 Q. Okay. It says, all documents including</p> <p>21 documents and deposition transcripts which you have</p> <p>22 received from any source.</p> <p>23 Now, you didn't -- are the -- if I</p> <p>24 remember right, you reviewed the deposition of Sarita</p> <p>25 Thapar and Misbah Sherwani; correct?</p>	<p>1 deposition and the exhibits to her deposition;</p> <p>2 correct?</p> <p>3 A. Yes.</p> <p>4 Q. So we're going to get that one off the</p> <p>5 table.</p> <p>6 A. Now, that had --</p> <p>7 Q. Now, you said "that," we have two</p> <p>8 notebooks. Let me -- which one did you want to refer</p> <p>9 to, Dr. Frank?</p> <p>10 A. The one where I removed the cover sheet,</p> <p>11 which I should not have done. I apologize.</p> <p>12 Q. So this is the smaller notebook you were</p> <p>13 talking about?</p> <p>14 A. It's the later. The one where I removed</p> <p>15 the cover was the first. There were cover sheets,</p> <p>16 similar cover sheets.</p> <p>17 Q. I have two notebooks. They each do have</p> <p>18 a Table of Contents; correct?</p> <p>19 A. Yes. Yes.</p> <p>20 Q. And did these both come at the same time</p> <p>21 or did they come at different times?</p> <p>22 A. Came at different times.</p> <p>23 Q. Which one came first, Dr. Frank?</p> <p>24 A. The one where I removed the cover.</p> <p>25 Q. Is that the larger one, the larger</p>
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<p>1 A. Yes. They're in these binders.</p> <p>2 Q. Okay. Do you --</p> <p>3 A. May I ask a question?</p> <p>4 Q. Do you know -- in a minute.</p> <p>5 Do you know which binder they're in,</p> <p>6 Dr. Frank?</p> <p>7 A. Right here and here (indicating).</p> <p>8 Q. Well, we're making progress, Dr. Frank.</p> <p>9 One of these notebooks, which says 1 of</p> <p>10 1 --</p> <p>11 A. Yeah.</p> <p>12 Q. -- contains the deposition of Misbah</p> <p>13 Sherwani and all of her exhibits to her deposition;</p> <p>14 correct?</p> <p>15 A. Uh-huh.</p> <p>16 Q. Is that right? Yes?</p> <p>17 A. Yes.</p> <p>18 Q. So we're going to get that notebook off</p> <p>19 the table. I'll put it back over with your material</p> <p>20 later. I just don't want to unhook from my --</p> <p>21 A. Yes.</p> <p>22 Q. And then another notebook, which says 1</p> <p>23 of 1, says Deposition of Sarita Thapar; correct?</p> <p>24 A. Yes.</p> <p>25 Q. And contained within it is her</p>	<p>1 notebook?</p> <p>2 And this notebook --</p> <p>3 MR. KAPLAN: You have to say yes or no.</p> <p>4 THE WITNESS: Yes.</p> <p>5 BY MR. DEAN:</p> <p>6 Q. It may not be relevant for our purposes</p> <p>7 later on, but this notebook has no markings on the</p> <p>8 outside. But it does have a Table of Contents on the</p> <p>9 inside, which we will -- which we will mark as an</p> <p>10 exhibit.</p> <p>11 MR. DEAN: And can you just give me an</p> <p>12 arbitrary exhibit number? Should we do something,</p> <p>13 start at -- call it 250, do you think?</p> <p>14 MS. TAKLA: Sure.</p> <p>15 MR. DEAN: Why don't we -- we will mark</p> <p>16 this later as Exhibit 250 so we don't have to go off</p> <p>17 camera right now.</p> <p>18 Make a note of that, please.</p> <p>19 BY MR. DEAN:</p> <p>20 Q. This notebook says, Digitek Expert Table</p> <p>21 of Contents. It has 18 items; correct?</p> <p>22 A. Yes.</p> <p>23 Q. Okay. And when -- and this was the</p> <p>24 first information you received; is that correct?</p> <p>25 A. Yes.</p>

11 (Pages 38 to 41)

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<p>1 Q. Do you recall approximately when you</p> <p>2 received this notebook?</p> <p>3 A. Sometime in the beginning of May.</p> <p>4 Q. And then what is the second, smaller</p> <p>5 notebook?</p> <p>6 A. That contains some of the additional</p> <p>7 documents that I requested.</p> <p>8 Q. So this has a document -- this has a</p> <p>9 Table of Contents that has 11 items; correct?</p> <p>10 A. May I say something?</p> <p>11 Q. Of course.</p> <p>12 A. I'm actually concerned that there's one</p> <p>13 more binder. But I moved these to the side of the</p> <p>14 office and stacked them specifically several weeks</p> <p>15 ago.</p> <p>16 There's a problem in that I cleaned out</p> <p>17 my closet with all of my old binders from my</p> <p>18 fellowship at the FDA, and I can't imagine that I</p> <p>19 mixed these binders in the stack with my old binders</p> <p>20 at the FDA, but I need to make you aware of that.</p> <p>21 Because I recall that I got more</p> <p>22 binders, and --</p> <p>23 Q. I'm sorry, you said you recall you got</p> <p>24 more binders?</p> <p>25 I want to make sure I heard you</p>	<p>1 Miller and Megan Carter at the Philadelphia Airport at</p> <p>2 either 12 o'clock or 1:00 p.m.</p> <p>3 Q. Doesn't matter what time you met.</p> <p>4 So that's the day you requested these</p> <p>5 documents; is that right?</p> <p>6 A. Yes.</p> <p>7 Q. Now, when you requested, did you -- did</p> <p>8 you hand them a list? Did you give them -- did you</p> <p>9 send them an e-mail?</p> <p>10 How did you convey the information to</p> <p>11 them?</p> <p>12 A. I had made a list for myself, and I</p> <p>13 believe that list is in here.</p> <p>14 Q. Okay. And then how shortly after that</p> <p>15 meeting did you receive the smaller notebook?</p> <p>16 A. It took a while. I think they were sent</p> <p>17 by FedEx ground, rather than FedEx overnight, because</p> <p>18 I called them twice concerned that there was a delay.</p> <p>19 MR. DEAN: Actually, you have exhibit</p> <p>20 stickers I see, don't you?</p> <p>21 Why don't you go ahead and we'll -- is</p> <p>22 it all right if I mark the original with the exhibit</p> <p>23 sticker?</p> <p>24 MR. THOMPSON: That's fine with me. I</p> <p>25 don't know the terms with this law firm. Can we make</p>
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<p>1 correctly. Did you say more?</p> <p>2 A. I'm trying to remember whether there was</p> <p>3 a fifth binder and I'm a little bit embarrassed.</p> <p>4 Q. Well --</p> <p>5 MR. THOMPSON: Let me say --</p> <p>6 BY MR. DEAN:</p> <p>7 Q. We'll come -- let me -- let me finish</p> <p>8 the questioning on this and we'll come back to that.</p> <p>9 Okay.</p> <p>10 So this one that says -- it has 11</p> <p>11 items, and we're going to mark this as Number 251, the</p> <p>12 Table of Contents. You said that it represents</p> <p>13 documents that you requested; is that correct?</p> <p>14 A. Yes.</p> <p>15 Q. Okay. And when did you make the -- when</p> <p>16 did you make that request?</p> <p>17 A. At a lunch meeting with Pete Miller, and</p> <p>18 I can check the date in my date book. Do you need the</p> <p>19 exact date?</p> <p>20 Q. Well, I would like to get an approximate</p> <p>21 -- yes, I would like -- yes, I would like to know when</p> <p>22 you made the request. Yes.</p> <p>23 If you've got a note on that, rather</p> <p>24 than guesstimating, that would be good.</p> <p>25 A. It was Wednesday, June 2nd. I met Pete</p>	<p>1 a copy here?</p> <p>2 MR. DEAN: Yes. We can get copies. I</p> <p>3 just want to get it marked so that --</p> <p>4 MR. THOMPSON: Yes, that would be --</p> <p>5 that's actually a good idea.</p> <p>6 MR. DEAN: Yes. If you'll give me an</p> <p>7 exhibit sticker, I'll go ahead and mark this so we</p> <p>8 don't get confused later on.</p> <p>9 (Exhibits D-250 and D-251 were marked</p> <p>10 for identification.)</p> <p>11 BY MR. DEAN:</p> <p>12 Q. And, Dr. Frank, we'll get copies for</p> <p>13 everyone later. But the larger notebook, the Table of</p> <p>14 Contents, I've marked as Exhibit 250.</p> <p>15 Do you see that?</p> <p>16 A. Yeah.</p> <p>17 Q. And that was the one you received</p> <p>18 initially; correct?</p> <p>19 A. Yes, in its entirety.</p> <p>20 Q. And then Exhibit 251 is the notebook you</p> <p>21 received after your meeting with Mr. Miller and</p> <p>22 Ms. Johnson; right?</p> <p>23 A. Yeah.</p> <p>24 Q. And then you said, I think you were just</p> <p>25 telling me, that somewhere in this other stack of</p>

12 (Pages 42 to 45)

<p style="text-align: right;">Page 46</p> <p>1 papers would be a list where you request -- you made</p> <p>2 the request for follow-up documents; is that right?</p> <p>3 Could you look and see if you could find</p> <p>4 that for me.</p> <p>5 A. These were the documents where I started</p> <p>6 listing what I did and did not have to review and</p> <p>7 tried to define what you might call the white space in</p> <p>8 the dossiers. They're not --</p> <p>9 Q. First of all, let me pause here. Let's</p> <p>10 stay on the question.</p> <p>11 Is there a document either which you</p> <p>12 handed to me or that you still have with you that</p> <p>13 represents a listing of the documents that are in the</p> <p>14 smaller notebook?</p> <p>15 A. No. I did not request those</p> <p>16 specifically. I talked to them about my concerns</p> <p>17 about what I called the white space or the absent</p> <p>18 documents in what I was sent, and they made the</p> <p>19 decision what additional documents to send me.</p> <p>20 Q. Okay. So then what is represented in</p> <p>21 the smaller notebook that's got Exhibit Number, on the</p> <p>22 Table of Contents, 251, is a selection of documents</p> <p>23 that Mr. Miller and Ms. Johnson sent to you after</p> <p>24 hearing general concerns about white space; correct?</p> <p>25 A. Yes. But I --</p>	<p style="text-align: right;">Page 48</p> <p>1 BY MR. DEAN:</p> <p>2 Q. All right. Let me hand you first what I</p> <p>3 marked as Number 252.</p> <p>4 Could you tell us what that is, please.</p> <p>5 A.</p> <p>6 These were notes to myself --</p> <p>7 Q. Please keep your voice up, too.</p> <p>8 A. These were notes to myself as I tried to</p> <p>9 define what was sent to me as far as the sequential</p> <p>10 FDA Establishment Inspection Reports, warning letters,</p> <p>11 the company responses and CAPAs, so that I was</p> <p>12 defining what I was going to be basing my opinions on.</p> <p>13 Q. Is that kind of a summary of the -- not</p> <p>14 of every document, but the kinds of material that you</p> <p>15 had received?</p> <p>16 A. Well, I got frustrated and concerned</p> <p>17 that I was being asked to render an opinion on what</p> <p>18 happened in a company, and I had only selected</p> <p>19 documents over the period.</p> <p>20 So I don't have the -- a lot of company</p> <p>21 responses and CAPAs. I don't know many things about</p> <p>22 the adequacy of their remediation plans.</p> <p>23 And then I actually -- this is a</p> <p>24 preliminary list. I didn't expect to give it to you.</p> <p>25 But I then started to sort out when I did this in my</p>
<p style="text-align: right;">Page 47</p> <p>1 Q. You -- just so we're clear, you did not</p> <p>2 give them this list?</p> <p>3 They made this selection based upon what</p> <p>4 you -- some concerns you had expressed; is that fair?</p> <p>5 A. Yes.</p> <p>6 Q. Okay.</p> <p>7 A. About those lists that I started to --</p> <p>8 Q. Hang on. I'll get to these. Okay?</p> <p>9 A. Okay.</p> <p>10 Q. We're just going to try to -- I'll try</p> <p>11 to ask a focused question, you try and give me an</p> <p>12 answer and stop, and then I'll ask you another</p> <p>13 question. Okay?</p> <p>14 A. Okay.</p> <p>15 Q. All right. Now, you have handed to</p> <p>16 me -- from the loose documents, you've handed to me</p> <p>17 looks like three different documents; is that correct?</p> <p>18 A. Uh-huh.</p> <p>19 Q. Yes?</p> <p>20 A. These were prepared --</p> <p>21 Q. Hold on.</p> <p>22 MR. DEAN: Let me mark these so we're</p> <p>23 clear so we don't get --</p> <p>24 (Exhibits D-252 through D-254 were</p> <p>25 marked for identification.)</p>	<p style="text-align: right;">Page 49</p> <p>1 comment document, the company's responses.</p> <p>2 How many letters went back and forth to</p> <p>3 -- between the health authorities and the company and</p> <p>4 what were the comments, the substantive issues in</p> <p>5 those.</p> <p>6 I did not go from here to here and say,</p> <p>7 oh, I found this warning letter. There could be</p> <p>8 inaccuracies in this. This was my preliminary list.</p> <p>9 Q. Could I just see that briefly, please.</p> <p>10 A. (Witness complies.)</p> <p>11 Q. Could you tell me briefly what 253 is.</p> <p>12 A. This -- these are notes that I took in</p> <p>13 writing the very early individual reports. And there</p> <p>14 are a lot of very close notes or verbatim transcripts</p> <p>15 of the documents as I went through them in</p> <p>16 excruciating detail.</p> <p>17 And then what I wanted -- what I should</p> <p>18 have done is asked for them up front electronically.</p> <p>19 But this became the basis of this report here.</p> <p>20 Q. So Exhibit 253 is a document you used</p> <p>21 when you were writing what we marked as Exhibit 50;</p> <p>22 correct?</p> <p>23 A. This could be considered an early draft</p> <p>24 of Exhibit 50.</p> <p>25 Q. Okay. Very good. Thank you.</p>

13 (Pages 46 to 49)

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1 And for the record, what is 254?

2 A. More notes to myself.

3 Q. Do you remember what -- what do they

4 generally represent?

5 A. I believe these are my notes from the

6 meeting with Mr. Miller and Ms. Carter on June 2nd.

7 Q. Could you read for me this particular

8 entry, it starts out documents, I think. And you

9 write pretty well, but I'm just having trouble reading

10 that.

11 A. Well, this is not that good. I wish

12 that -- if I had known that these were going to be

13 given to you, I would have notated them much more

14 carefully.

15 Q. Just try to, as best you can, read that

16 one sentence for me.

17 A. It says, preponderance of the evidence,

18 civil.

19 Q. Excuse me.

20 A. Right above that?

21 Q. Yes. That one right there.

22 A. Document for withholding.

23 Q. Do you know what thought you were trying

24 to capture there? And if you don't, just tell me.

25 A. I think it's the time that I decided --

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1 this may have been to myself -- that this situation

2 was so convoluted, I wanted a document that would

3 allow me to carefully track the absence of information

4 on specific ADE's complaints or investigations.

5 Because of this type of situation and

6 the complexity of what happened in the company, the

7 intermittent evidence that was presented, the fact

8 that there's things that I would have liked to have

9 seen that we couldn't obtain, that I wanted to

10 carefully track that for this very situation, so I

11 could present to you what I had, what I did not have,

12 and track the opinions very, very closely to what I

13 was able to see.

14 Q. Did you ever submit to the plaintiffs a

15 listing of documents you thought you were missing that

16 you specifically wanted them to provide to you?

17 A. I gave Pete Miller some notes from the

18 meeting as I was talking in generalities. I don't

19 remember that was -- if that was on the back of the

20 list. I don't -- I did not type up a specific list.

21 I believe I showed him these.

22 Q. These being what? Which exhibit number?

23 A. These preliminary assessments of the

24 white space.

25 Q. Being Number 252?

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1 A. Yes.

2 Q. Okay. Let me go back to my question

3 because my question I think was focused. I think

4 you've come close to answering it.

5 But did you give a specific list of

6 documents to Mr. Miller to fill -- which, in your

7 mind, would fill out what you are calling the white

8 space that you wanted to be provided?

9 A. I think I had the list in front of me

10 and I read down it. I may have translated a few of

11 those to another paper, but he responded to my going

12 down the list what was and was not available at that

13 point in discovery.

14 The fact that discovery was complete and

15 then there was discussion of there may be another

16 round of discovery and the possibility of obtaining

17 those documents.

18 But I did not type up a list or write up

19 a specific list that I handed to him. And I can't

20 recall the specifics of the exchange. A lot of this

21 was my asking questions of them.

22 How do I prepare these documents for

23 expert witness and can I get any of these?

24 I would have these if I was an FDA

25 medical officer. I would have some of this

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1 information if I was inside the company and helping

2 with the remediation.

3 Can you get this for me now so my

4 opinion can be based on a broader and more complete

5 compilation of the evidence?

6 Q. Can we agree, then, that you never gave

7 Mr. Miller or any plaintiff's lawyer a specific list

8 of documents that you wanted to look at?

9 Can we agree on that?

10 A. Yes. And next time I will very

11 carefully.

12 MR. THOMPSON: Dick, I can put an

13 exhibit right here. That's the -- you got that;

14 right?

15 MR. DEAN: Right.

16 MR. THOMPSON: Okay.

17 (Exhibit D-255 was marked for

18 identification.)

19 BY MR. DEAN:

20 Q. I'm handing you what I've marked as

21 Defendant Exhibit 255, which is entitled Documents

22 sent to Karen Frank, and it has 29 items listed on it.

23 And I see that 250 and 251, one has 18

24 and one has 11, so that would be 29.

25 Is life so good for Mr. Thompson and me

14 (Pages 50 to 53)

Karen A. Frank, M.D.

Videotaped

June 30, 2010

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1 that Exhibit 255 is simply a compilation of the Table
2 of Contents of these other two notebooks?
3 A. I believe so. I called their admins to
4 ask about these, and I think about this one.
5 Q. First of all, you --
6 A. Yes.
7 Q. I want to give you the opportunity, but
8 do you -- if you need to look at it, but is 255 simply
9 a compilation of what we have on the Table of Contents
10 on 250 and 251?
11 A. I believe so, but I specifically did not
12 check. I did not bill them for time verifying this
13 against either of those binders or against the
14 electronic.
15 Q. When was 250 -- did you prepare 255 or
16 did someone else?
17 A. Someone else did.
18 Q. Do you know who did?
19 A. One of the admins or paralegals at the
20 Miller firm.
21 Q. Okay. Why don't you let me have that
22 one back.
23 A. (Witness complies.)
24 Q. Now, you just pointed out that there's
25 some handwriting in red ink on here. Is that your

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1 handwriting?
2 A. No. That's from the admins at the firm.
3 Q. Okay.
4 (Exhibit D-256 was marked for
5 identification.)
6 BY MR. DEAN:
7 Q. What is 256?
8 A. That is my notes from a discussion with
9 Smart Consulting about the way another expert
10 consultant approached review of the cases.
11 Q. And that consultant would be Mr. Farley?
12 A. Yes.
13 Q. When -- is this in your handwriting?
14 A. Yes.
15 Q. And who did you speak to?
16 A. On the telecon were Denise Smart, Nigel
17 Smart, and Jim Farley.
18 Q. And what was the occasion for the four
19 of you to speak to each other?
20 A. Remember earlier I said that I had been
21 approached about doing this kind of work in the past?
22 Q. Yes.
23 A. Well, I had declined it. And Smart
24 Consulting approached me about doing this expert
25 witness work.

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1 I was a little loathed to move in to
2 litigation. And this was the first time I had done
3 any expert witness work. I was not certain how to
4 prepare the documents, how to format the documents.
5 I prepared FDA reviews, I prepared
6 things to go to the health authorities, but I was
7 asking him questions about being an expert witness and
8 trying to determine if I was going to tactfully
9 decline this engagement and simply not undertake
10 expert witness work.
11 And I had discussions with Mr. Miller
12 and with Megan Carter in sorting out, you know, how to
13 proceed with the work. So there was coaching and
14 advice as I began to develop a way to develop these
15 documents.
16 I asked them for copies of Jim Farley's
17 documents so I could format them appropriately. And
18 they did not want to do that because they were in
19 draft.
20 So they gave me indications of how they
21 wanted the documents formatted.
22 So what you're seeing is indication of
23 somebody who had not previously done expert witness
24 work taking on assignment and being rather transparent
25 with the consulting firm and the attorneys as to my

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1 present state of experience with this and getting
2 advice on how to proceed.
3 Q. Did Smart -- are you working through
4 Smart Consulting in this litigation?
5 A. Yes.
6 Q. Did they recruit you for this
7 assignment?
8 A. Yes.
9 Q. Had they already recruited Mr. Farley?
10 A. Yes.
11 Q. Was Smart Consulting the first company
12 that approached you about taking on this assignment?
13 A. Yes.
14 Q. And when was that?
15 A. I don't recall the date, but I do have a
16 signed copy of the Consulting Agreement.
17 Q. Is that in the documents we have here?
18 A. Yes. I scanned it with my date of
19 signature.
20 Q. Where is it? Is it in one of --
21 A. You have a scanned electronic copy of
22 this document. That was the one that was faxed to
23 Smart Consulting.
24 You need that copy?
25 MR. DEAN: Yes.

15 (Pages 54 to 57)

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Karen A. Frank, M.D.

Videotaped

June 30, 2010

<p style="text-align: right;">Page 58</p> <p>1 MR. THOMPSON: Well, that's your 2 original? 3 THE WITNESS: It's my original. 4 MR. DEAN: Well, you're going to get it 5 back, just with an exhibit sticker on it. Is that 6 okay? 7 THE WITNESS: Yes. Whatever you need. 8 (Exhibit D-257 was marked for 9 identification.) 10 BY MR. DEAN: 11 Q. So 257 is a copy of that agreement; 12 correct? 13 A. Yes. 14 Q. Had you ever -- before this agreement, 15 had you ever done anything with Smart Consulting? 16 A. I provided them with some business 17 processes for a proposal in 2009 on product 18 complaints. 19 I believe I was recruited to be on a 20 proposal for another consulting assignment, and for 21 confidentiality, I don't think I can tell you what the 22 client was. 23 But I did not provide any information to 24 Smart. They had two spots that I could possibly fit 25 in and there was a phone conversation as to how I</p>	<p style="text-align: right;">Page 60</p> <p>1 A. Yes. 2 Q. Is there some reason why it was removed 3 from the notebook? 4 A. It wasn't deliberate. What I have are 5 the loose documents in a stack and the notebooks. But 6 there -- no, there was no -- I did not cite that or 7 the injunction or the consent decrees in my reports. 8 It was reviewed initially, possibly 9 reviewed twice, but I did not use it as evidence. 10 Q. Are these separate pages or are these 11 one document? 12 A. They're separate. 13 (Exhibits D-259 and D-260 were marked 14 for identification.) 15 BY MR. DEAN: 16 Q. What is Defendant 259? 17 A. I was trying to sort out what was the 18 business process in the company for evaluation of out 19 of spec results, product complaints. 20 There was no evidence provided to me 21 that the work that I did in industry of doing routine 22 Health Hazard Assessments was being done, and I wasn't 23 certain whether it was just that I didn't receive the 24 documents. 25 But when I've done work for clients</p>
<p style="text-align: right;">Page 59</p> <p>1 would fit best into that engagement. 2 And then I did some work on a REMS 3 proposal for them back probably in March of 2010 where 4 we did not win the engagement. 5 And it was on the basis of those 6 interactions that they approached me about being an 7 expert witness on this case. 8 And Nigel Smart was very adamant that 9 based on his interaction with me that he thought that 10 my background was completely adequate to make 11 substantive comment on what would be sent to me and 12 that it was an appropriate assignment. 13 Q. Is Nigel Smart an attorney? 14 A. No. He's a Ph.D. who has done this 15 work. 16 (Exhibit D-258 was marked for 17 identification.) 18 BY MR. DEAN: 19 Q. What's Defense Exhibit 258? 20 A. That was part of the background that was 21 submitted in the first binder. 22 Q. So this is a document prepared by one of 23 the plaintiffs' attorneys and would have been 24 contained within the notebook where we have the 25 Exhibit Number 250 is the Table of Contents?</p>	<p style="text-align: right;">Page 61</p> <p>1 who've been inside companies and there is a 2 manufacturing deviation, particularly if it's released 3 in the market, I would usually get a copy of an 4 investigation where if they had a sample of the 5 product, they would bring it back in-house and do 6 analytics. 7 If they needed to, they would check it 8 for bacteriology. They would then go back and do an 9 investigation in the plant, you know, a real root 10 cause analysis. 11 I would be provided with an 12 investigation report that would define the batches at 13 risk for a single drug or even if multiple drugs had 14 been through that piece of malfunctioning equipment. 15 Q. This would be a product complaint you're 16 talking about? 17 A. Yes, in another company. 18 Q. Right. 19 And just so I'm clear, you're talking 20 about in other companies you work for where there was 21 a product complaint, there would be a system in place 22 where a complaint form would be generated and 23 processed through the system; is that correct? 24 A. Yes. 25 Q. Okay.</p>

16 (Pages 58 to 61)

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<p>1 A. And --</p> <p>2 Q. And did you -- did you make any inquiry</p> <p>3 in this case as to whether there were product</p> <p>4 complaint forms that you could look at and see how</p> <p>5 they were processed?</p> <p>6 Did you ask the plaintiffs' lawyers for</p> <p>7 that type of information?</p> <p>8 A. Yes, I did. I commented on June 2nd on</p> <p>9 the absence of this information, and --</p> <p>10 Q. Let me just ask you, did the plaintiffs'</p> <p>11 lawyers ever provide to you any product complaints on</p> <p>12 Digitek?</p> <p>13 A. Yes. But I believe they were after the</p> <p>14 recall. What I did receive was the investigation</p> <p>15 report of the double-thick tablet of Digitek. The</p> <p>16 complaint registered by a pharmacist in Bellingham,</p> <p>17 Washington, in July of 2004.</p> <p>18 Q. I'll get back to that. I don't want to</p> <p>19 -- heeding Mr. Thompson's admonition, I don't want to</p> <p>20 repeat myself.</p> <p>21 But let me just ask you: As I</p> <p>22 understood it, you asked for product complaints on</p> <p>23 Digitek before the recall, also, didn't you?</p> <p>24 A. They were not on my list. I didn't say</p> <p>25 product complaints that I can recall specifically.</p>	<p>1 in the investigation of product complaints, which I've</p> <p>2 never done.</p> <p>3 I received the results to write the</p> <p>4 Health Hazard Assessments. So my absence of asking</p> <p>5 for them may have been my assumption of where they</p> <p>6 were to be directed.</p> <p>7 MR. DEAN: Okay. Let's take a break.</p> <p>8 Our tape needs to be changed. We'll get</p> <p>9 some copies of exhibits and we can all stand up and</p> <p>10 walk around a little bit.</p> <p>11 Let's go off the record.</p> <p>12 THE WITNESS: Okay.</p> <p>13 VIDEO OPERATOR: Going off the video</p> <p>14 record.</p> <p>15 This is the end of Tape 1.</p> <p>16 The time is 10:27 a.m.</p> <p>17 (A recess was taken from 10:27 a.m. to</p> <p>18 10:43 a.m.)</p> <p>19 VIDEO OPERATOR: We're now back on the</p> <p>20 video record.</p> <p>21 This is the start of Tape 2.</p> <p>22 The time is 10:43 a.m.</p> <p>23 BY MR. DEAN:</p> <p>24 Q. Dr. Frank, I think we just have a couple</p> <p>25 more documents to mark and have you identify and then</p>
Page 63	Page 65
<p>1 Q. So you did not -- so just so I'm clear,</p> <p>2 you did not ask the plaintiffs' lawyers to provide</p> <p>3 product complaints on Digitek prior to the recall; is</p> <p>4 that correct?</p> <p>5 A. I believe they were volunteered. What I</p> <p>6 was looking for was investigation reports of product</p> <p>7 complaints and realtime Health Hazard Assessments,</p> <p>8 which would have been generated from those product</p> <p>9 complaint reports.</p> <p>10 Q. Did you ask for product complaints on</p> <p>11 Digitek prior to the recall? Yes or no?</p> <p>12 A. I would have to say no, unless you would</p> <p>13 consider it implied in asking for evidence that would</p> <p>14 confirm that those business processes were in place</p> <p>15 and in use during this period.</p> <p>16 Q. Okay. So -- but you didn't specifically</p> <p>17 ask for them; correct?</p> <p>18 A. No.</p> <p>19 Q. Okay. Fine.</p> <p>20 A. May I?</p> <p>21 Q. You can go ahead and say whatever you'd</p> <p>22 like to say.</p> <p>23 A. It may be a result of my naivete, and I</p> <p>24 assumed that these were manufacturing issues and they</p> <p>25 were going to another consultant whose expertise was</p>	<p>1 we'll get into the substance of this.</p> <p>2 I don't think I've asked you what Number</p> <p>3 260 is.</p> <p>4 A. This is more notes.</p> <p>5 Q. And do you know what day you took those</p> <p>6 notes, what the occasion was for taking those notes?</p> <p>7 A. I'm trying to remember whether I made</p> <p>8 them before or after the meeting with Pete Miller on</p> <p>9 the 2nd.</p> <p>10 As I said, I was coached somewhat into</p> <p>11 how to leverage my FDA experience, my industry</p> <p>12 experience, to produce work products for attorneys as</p> <p>13 an expert witness.</p> <p>14 And I actually started this project with</p> <p>15 my, what I'll say, my modus operandi as an FDA medical</p> <p>16 officer.</p> <p>17 And then I started to tease out what I</p> <p>18 could about what was going on inside these companies,</p> <p>19 what business processes were in place and in use.</p> <p>20 And I brought some of these notes to the</p> <p>21 meeting with Mr. Miller and Ms. Carter, and there were</p> <p>22 some that I made.</p> <p>23 And I started to explain to them my</p> <p>24 concerns that I couldn't piece together things from</p> <p>25 the FDA inspections. And then they provided me more</p>

17 (Pages 62 to 65)

<p style="text-align: right;">Page 66</p> <p>1 documents where the FDA clearly documented things.</p> <p>2 And that's the basis of this large</p> <p>3 document, it's finding the answers to these questions</p> <p>4 or any information that elucidated how -- are these</p> <p>5 business processes in place. So these are my notes to</p> <p>6 myself.</p> <p>7 Q. Taken at a meeting with Mr. Miller; is</p> <p>8 that right?</p> <p>9 A. Or sketched at a meeting with Mr. Miller</p> <p>10 to say these are things that typically occur in a</p> <p>11 company and what -- while I'm looking at inspection</p> <p>12 reports that are samplings of compliance with SOPs, I</p> <p>13 don't have any SOPs or work flows and I'm trying to</p> <p>14 piece together what was in place and in use from the</p> <p>15 FDA reports and the warning letters.</p> <p>16 And that's when I asked for more</p> <p>17 information to start to give myself a clearer picture.</p> <p>18 Q. Okay. You also brought with you a copy</p> <p>19 of Plaintiff's Exhibit 91, which is a 2008 IDR.</p> <p>20 You also brought a -- in your papers was</p> <p>21 a February 28, 2006 letter from Amide to the FDA;</p> <p>22 correct?</p> <p>23 A. Yes. Now --</p> <p>24 Q. No, no. That's -- that was -- that's --</p> <p>25 you've answered the question.</p>	<p style="text-align: right;">Page 68</p> <p>1 A. Yes. I said something earlier about</p> <p>2 possibly having five binders. I think this was my</p> <p>3 fifth. This was the last thing delivered, and --</p> <p>4 Q. By this, you are holding up Exhibit 91;</p> <p>5 correct?</p> <p>6 A. Yes. This was the last thing that Pete</p> <p>7 Miller sent to me by FedEx. I'm not sure why it</p> <p>8 wasn't in the others, but this is a very key</p> <p>9 inspection report to piecing together what happened</p> <p>10 and it was the last piece of information to arrive.</p> <p>11 MR. THOMPSON: Let me see if I can</p> <p>12 satisfy the defendants with regard to the fifth</p> <p>13 binder. My understanding is that you think there may</p> <p>14 be a fifth binder. You're not certain.</p> <p>15 If I can just simply say, we will go and</p> <p>16 make a diligent search, and if we uncover a fifth</p> <p>17 binder that's been placed in another binder, we will</p> <p>18 make that available to the defense and we will</p> <p>19 certainly give you an opportunity to question her</p> <p>20 either by telephone or by reconvening the deposition.</p> <p>21 Is that --</p> <p>22 MR. DEAN: That's acceptable. Thank</p> <p>23 you.</p> <p>24 MR. THOMPSON: All right.</p> <p>25 BY MR. DEAN:</p>
<p style="text-align: right;">Page 67</p> <p>1 A. All right.</p> <p>2 Q. And then you brought a three-page</p> <p>3 document, which is a Actavis document, that bears the</p> <p>4 Bates label 65400 through 65402; is that correct?</p> <p>5 A. Yes.</p> <p>6 Q. And is it fair to say that we have now</p> <p>7 reviewed all the documents that you brought with you</p> <p>8 today?</p> <p>9 A. Yes.</p> <p>10 Q. But?</p> <p>11 A. I believe this document may have been</p> <p>12 taken from a binder and not been appropriately</p> <p>13 reinserted because it is a punched document.</p> <p>14 Q. Correct. So that's the February 28,</p> <p>15 2006 document.</p> <p>16 So you're suggesting it may actually go</p> <p>17 in one of the notebooks that we looked at previously;</p> <p>18 correct?</p> <p>19 A. Yes.</p> <p>20 Q. Okay. Now, is it fair to say, having</p> <p>21 gone through all of these documents, that you have</p> <p>22 brought -- that the items we've just gone over would</p> <p>23 be all the information that you would have in response</p> <p>24 to Exhibit 90, which is the Notice for Video</p> <p>25 Deposition Duces Tecum?</p>	<p style="text-align: right;">Page 69</p> <p>1 Q. And as I understand it, as you sit here</p> <p>2 today, you're not sure whether there was another</p> <p>3 binder or not?</p> <p>4 A. I'm embarrassing myself that I didn't</p> <p>5 keep a clear catalog. But I -- when I finished this</p> <p>6 report, I gathered everything up and I put it over to</p> <p>7 the side. And I, for some reason, am really -- it's</p> <p>8 just bothering me.</p> <p>9 And so I'm willing to embarrass myself</p> <p>10 and say, you know, I had this idea there were five,</p> <p>11 but, to my knowledge, everything that I used for this</p> <p>12 report is in front of us.</p> <p>13 But I would sure appreciate to make sure</p> <p>14 that I didn't accidentally file this with something</p> <p>15 else.</p> <p>16 MR. THOMPSON: All right.</p> <p>17 MR. DEAN: We'll ask you to follow up on</p> <p>18 that and if you find something, and Mr. Thompson will</p> <p>19 look at his records, and if there is a fifth notebook,</p> <p>20 it's my understanding that the defendants will be</p> <p>21 informed of that.</p> <p>22 THE WITNESS: Yes.</p> <p>23 MR. DEAN: So we can go ahead.</p> <p>24 (Exhibit D-261 was marked for</p> <p>25 identification.)</p>

18 (Pages 66 to 69)

Karen A. Frank, M.D.

Videotaped

June 30, 2010

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<p>1 BY MR. DEAN:</p> <p>2 Q. And just out of the -- for the sake of</p> <p>3 caution, we have marked as Exhibit 261 the color copy</p> <p>4 of your report, and I have a copy for Mr. Thompson and</p> <p>5 for Mr. Kaplan because it may assist us as we proceed</p> <p>6 here this afternoon.</p> <p>7 A. Okay.</p> <p>8 MR. DEAN: Harvey.</p> <p>9 BY MR. DEAN:</p> <p>10 Q. Okay. What do you conceive your role to</p> <p>11 be as an expert witness in this case?</p> <p>12 A. I was asked to comment on two things:</p> <p>13 The adequacy of the pharmacovigilance processes and</p> <p>14 the impact on any signal detection in regard to the</p> <p>15 Digitek case.</p> <p>16 It was -- I was asked only on the</p> <p>17 systems. I was not provided any information on the</p> <p>18 content, the MedWatch, the PSURs, that would allow me</p> <p>19 to actually do the signal detection or the trending.</p> <p>20 The scope of my work was limited.</p> <p>21 I was also asked to comment on changes</p> <p>22 in the risk communication that occurred between the</p> <p>23 Health Hazard Assessment of Dr. Leikin, the letter to</p> <p>24 the Dear Customer, the business-to-business letter to</p> <p>25 Mylan and UDL, and then the public press release.</p>	<p>1 evaluated.</p> <p>2 And then when you read the conclusions,</p> <p>3 that would be the final. And I cannot guarantee you</p> <p>4 that every single comment in this document has been</p> <p>5 extracted into the conclusion.</p> <p>6 Q. Dr. Frank, are all of your conclusions</p> <p>7 in Exhibit 261?</p> <p>8 A. Yes.</p> <p>9 Q. And all of your observations about this</p> <p>10 case would be included in either Exhibit 50 and</p> <p>11 Exhibit 261; correct?</p> <p>12 A. Yes.</p> <p>13 Q. Thank you.</p> <p>14 A. Now, please -- yes or no? Okay.</p> <p>15 MR. THOMPSON: Just let Dick ask you a</p> <p>16 question.</p> <p>17 BY MR. DEAN:</p> <p>18 Q. So we can agree that you did not look at</p> <p>19 the underlying -- any underlying AER reports on</p> <p>20 Digitek; correct?</p> <p>21 A. I did not receive any MedWatch forms or</p> <p>22 CIOMS forms. I did not receive any PSURs, any U.S.</p> <p>23 Periodic Reports, or any other aggregate reports to</p> <p>24 any health authority.</p> <p>25 MR. KAPLAN: I can't hear you.</p>
Page 71	Page 73
<p>1 I could not find any evidence of Dear</p> <p>2 Doctor or Dear Patient letters.</p> <p>3 So when I was asked to look at the</p> <p>4 changes in those communications, I documented that</p> <p>5 absence and said, I am going from Health Hazard</p> <p>6 Assessment to a business-to-business Dear Customer</p> <p>7 letter, and then the communication to the health care</p> <p>8 community and the patients is restricted to the press</p> <p>9 release.</p> <p>10 There is not additional communication in</p> <p>11 the form of Dear Doctor and Dear Patient letters. My</p> <p>12 comments are restricted to those two spheres and then</p> <p>13 merged into one document with the supporting evidence.</p> <p>14 Q. Does Exhibit 261 contain all of your</p> <p>15 opinions in this case?</p> <p>16 A. This is the conclusion. There are</p> <p>17 comments in the supporting document that are also</p> <p>18 expressions of opinions. It is possible that all of</p> <p>19 the comments in the supporting document have not been</p> <p>20 completely abstracted to the conclusion.</p> <p>21 Because my original intent was to</p> <p>22 provide this document with this conclusion following</p> <p>23 this, so that you would go through this seeing the</p> <p>24 timeline that also notes some of the absences of</p> <p>25 information, and then the information that I read and</p>	<p>1 THE WITNESS: I did not receive any</p> <p>2 MedWatch forms, any CIOMS forms, any PSURs, ICH PSURs,</p> <p>3 no U.S. Periodic Reports, or any other form of</p> <p>4 aggregate reporting to the health authorities.</p> <p>5 The only information that I received was</p> <p>6 Dr. Leikin's final health assessment, Health Hazard</p> <p>7 Assessment, and FDA -- FDA inspection 483s,</p> <p>8 Establishment Inspection Reports, and the resultant</p> <p>9 letters between the FDA and Actavis or Amide.</p> <p>10 BY MR. DEAN:</p> <p>11 Q. And I don't want to harp on this, but I</p> <p>12 asked -- this is for furtherance of our proceedings</p> <p>13 today, I simply asked whether you had received the</p> <p>14 MedWatch, the AERs and the MedWatch reports.</p> <p>15 You told me no. And then you went on</p> <p>16 and gave me a whole other list of things.</p> <p>17 I would simply ask that, as we go along</p> <p>18 today, you listen to my question and answer my</p> <p>19 question. Is that agreeable?</p> <p>20 A. Yes.</p> <p>21 Q. Okay. Thank you.</p> <p>22 And so since you did not have the</p> <p>23 MedWatch forms in regard to Digitek, you would have</p> <p>24 necessarily been unable to engage in any signal</p> <p>25 detection analysis; correct?</p>

19 (Pages 70 to 73)

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<p style="text-align: right;">Page 74</p> <p>1 MR. THOMPSON: Object to the form.</p> <p>2 BY MR. DEAN:</p> <p>3 Q. Go ahead, Doctor. You can answer the</p> <p>4 question.</p> <p>5 A. I'm going to say yes, it precludes</p> <p>6 definitive assessment. The reason I went on too long</p> <p>7 with your original question is to list all of the</p> <p>8 documents that I could recall that contain any</p> <p>9 information abstracted from the MedWatches.</p> <p>10 What I received, and I did discuss this</p> <p>11 with them last night, was abstracted information that</p> <p>12 was usually the coding, the ADR coding, that really</p> <p>13 precluded definitive assessment of any single case and</p> <p>14 really any aggregate analysis.</p> <p>15 Q. So you didn't have the information to do</p> <p>16 that, did you?</p> <p>17 A. No. The only thing I had provided to me</p> <p>18 was Dr. Leikin's Health Hazard Assessment where I</p> <p>19 could use the information that he provided in that to</p> <p>20 assess his conclusions.</p> <p>21 But I felt that report did not contain</p> <p>22 enough detail to allow me to make a full, independent</p> <p>23 assessment, in that he included only a table of the</p> <p>24 events and I was not given as an appendix to that the</p> <p>25 company internal signal detection report that he was</p>	<p style="text-align: right;">Page 76</p> <p>1 submitted to the FDA, they list events.</p> <p>2 The assumption is that when the FDA is</p> <p>3 talking about adverse events, whether they be 15-day</p> <p>4 reports that are not submitted or adverse events that</p> <p>5 -- where they did not like the adequate -- the</p> <p>6 adequacy of the narrative quality or the follow-up,</p> <p>7 when they list the event, the date, the drug, and the</p> <p>8 -- I'm sorry -- the case number, the date and the drug</p> <p>9 and then the events that follow, the assumption is</p> <p>10 that that is the coding that was done on the</p> <p>11 narrative, the events associated with the MedWatch.</p> <p>12 They do comment that there were problems</p> <p>13 with the events being left out of the appropriate box</p> <p>14 of the MedWatch.</p> <p>15 Q. Is what you have described, does it</p> <p>16 contain actual coding or does it contain -- or is it</p> <p>17 -- are they documents from which you've assumed a</p> <p>18 coding?</p> <p>19 A. It is an assumption on my part. I</p> <p>20 have --</p> <p>21 Q. So -- so the only -- let's get back to</p> <p>22 my original question.</p> <p>23 The only coding on MedWatches that you</p> <p>24 have seen is what is contained in the Health Hazard</p> <p>25 Evaluation form; is that correct?</p>
<p style="text-align: right;">Page 75</p> <p>1 provided.</p> <p>2 Q. You said a minute ago that you had seen</p> <p>3 some coding on the MedWatch reports.</p> <p>4 What coding did you see and in what</p> <p>5 document did you see it?</p> <p>6 A. The coding would be in the table of</p> <p>7 Dr. Leikin's Health Hazard Assessments where he has</p> <p>8 the events. My assumption is that the events listed</p> <p>9 were events coded.</p> <p>10 I do not know that he did not go to the</p> <p>11 narrative and take out events that were not coded. I</p> <p>12 am making an assumption. There are similar</p> <p>13 abstractions in the --</p> <p>14 Q. Excuse me. Let me just stop you.</p> <p>15 So the only coding -- I want to -- focus</p> <p>16 on my question.</p> <p>17 The only coding was what is in the</p> <p>18 Health Hazard Evaluation form that Dr. Leikin did;</p> <p>19 whatever codes appear there are the only codes you've</p> <p>20 seen on MedWatch reports; is that correct?</p> <p>21 A. No.</p> <p>22 Q. Okay. What else have you seen?</p> <p>23 A. The FDA inspectors, when they go back</p> <p>24 through the cases, and this is in the supporting</p> <p>25 documents, when they cite the cases that were not</p>	<p style="text-align: right;">Page 77</p> <p>1 A. And I am --</p> <p>2 Q. Is that correct?</p> <p>3 A. I have to clarify the yes or no because</p> <p>4 you --</p> <p>5 Q. Well, could you answer first before you</p> <p>6 clarify?</p> <p>7 This is very simple. Have you seen any</p> <p>8 coding on a MedWatch report on Digitek other than what</p> <p>9 may be contained in that Health Hazard Evaluation</p> <p>10 form?</p> <p>11 A. I have not seen any MedWatch forms with</p> <p>12 coding. I made the assumption that Dr. Leikin</p> <p>13 constructed the table in the Health Hazard Assessments</p> <p>14 from the coding on the cases.</p> <p>15 But I was not able to verify that table</p> <p>16 against the coding on the MedWatch forms.</p> <p>17 MR. DEAN: Excuse me. There's one with</p> <p>18 just the Health Hazard Evaluation, the document.</p> <p>19 BY MR. DEAN:</p> <p>20 Q. Dr. Frank, I have -- I hand you --</p> <p>21 VIDEO OPERATOR: Your microphone.</p> <p>22 BY MR. DEAN:</p> <p>23 Q. I hand you what we've marked as Exhibit</p> <p>24 220, and it contains the Health Hazard Evaluation</p> <p>25 form; correct?</p>

20 (Pages 74 to 77)

<p style="text-align: right;">Page 78</p> <p>1 A. Yes.</p> <p>2 Q. And the -- you've been talking about</p> <p>3 coding. Are you referring to the chart?</p> <p>4 A. When you look at the table here -- well,</p> <p>5 actually, what I'm really referring to is the table.</p> <p>6 The column that says, Adverse Events,</p> <p>7 and they list these, my assumption is that these</p> <p>8 events will map to the adverse events on the CIOMS or</p> <p>9 the MedWatch forms and the coding in the database.</p> <p>10 Q. And so that's what you meant before by</p> <p>11 seeing information about coding, you are referencing</p> <p>12 to this table in Exhibit 220; correct?</p> <p>13 A. That, and the FDA inspector's similar</p> <p>14 abstractions of events that most likely will map to</p> <p>15 coding on the MedWatch forms and coding in the adverse</p> <p>16 event databases.</p> <p>17 Q. Okay. Let's go on.</p> <p>18 How much are you being paid for your</p> <p>19 services in this matter?</p> <p>20 A. \$150 an hour.</p> <p>21 Q. How much time have you spent on this</p> <p>22 matter?</p> <p>23 A. Initially, I worked to like -- the first</p> <p>24 week I worked about 35 hours and then I spoke to Smart</p> <p>25 Consulting about how much time they were expecting.</p>	<p style="text-align: right;">Page 80</p> <p>1 A. Yes.</p> <p>2 Q. Well, I -- a few minutes ago I asked you</p> <p>3 about the scope, your understanding about what your</p> <p>4 assignment was, and you told me the two topics that</p> <p>5 you were asked to address.</p> <p>6 What do you understand your role to be</p> <p>7 in this case as far as how you present the</p> <p>8 information?</p> <p>9 Do you view yourself as an advocate on</p> <p>10 behalf of the plaintiffs or do you view yourself as an</p> <p>11 impartial truth seeker?</p> <p>12 MR. THOMPSON: Object to the form.</p> <p>13 BY MR. DEAN:</p> <p>14 Q. Go ahead.</p> <p>15 A. I have particular concern, because this</p> <p>16 is the first time I've been an expert witness, that my</p> <p>17 opinions are based on very, very accurate and very,</p> <p>18 very complete evidence.</p> <p>19 I became very, very uncomfortable with</p> <p>20 the lack of detail in the evidence and the absence of</p> <p>21 information to -- that I was provided to completely</p> <p>22 evaluate the systems in the company.</p> <p>23 And what I decided to do to make this</p> <p>24 initial assessment as accurate as possible was to</p> <p>25 track very, very closely with FDA inspectors'</p>
<p style="text-align: right;">Page 79</p> <p>1 And they said there was no cap.</p> <p>2 And I said, well, the convention on --</p> <p>3 is either a 40-hour cap, a 50-hour cap or a 60-hour</p> <p>4 cap. And they instructed me to work to a 60-hour cap.</p> <p>5 At the end, I was provided these</p> <p>6 additional -- the additional documents in a short time</p> <p>7 frame, and I worked extra hours.</p> <p>8 And then I talked to Smart Consulting</p> <p>9 about whether I should bill over the cap, and they</p> <p>10 instructed me to bill it.</p> <p>11 Q. So as you --</p> <p>12 MR. KAPLAN: Instructed you to what? I</p> <p>13 can't hear you. I'm sorry.</p> <p>14 THE WITNESS: I billed over the 60-hour</p> <p>15 cap.</p> <p>16 MR. KAPLAN: How many?</p> <p>17 BY MR. DEAN:</p> <p>18 Q. So, as you sit here today, how much time</p> <p>19 have you billed to this matter?</p> <p>20 A. I did not do an aggregate analysis of</p> <p>21 the time. It is included on this, all of the time</p> <p>22 sheets.</p> <p>23 Q. So when we take one of these with us</p> <p>24 today, when Mr. Thompson and I each take one, we'll</p> <p>25 have that information; is that correct?</p>	<p style="text-align: right;">Page 81</p> <p>1 observations that were made by looking at primary</p> <p>2 documents that I was not provided.</p> <p>3 And what I have been hired by the</p> <p>4 plaintiffs, I want to make sure that my opinions are</p> <p>5 as accurate as possible.</p> <p>6 It's been a little bit embarrassing when</p> <p>7 you asked me questions and you see that I'm doing --</p> <p>8 sketching notes to myself. I don't write out official</p> <p>9 lists and hand them to the attorneys.</p> <p>10 I want as little, I want to say,</p> <p>11 embarrassment as possible, that will result from my</p> <p>12 handling what I see as somewhat of a difficult case.</p> <p>13 And this being the first time that I've</p> <p>14 done this, I don't have experience in having done this</p> <p>15 before. And I have concerns about the incompleteness</p> <p>16 of the information.</p> <p>17 There's a fair amount of additional</p> <p>18 information, such as MHRA inspections, which are very</p> <p>19 vigorous inspections on compliance, maybe more</p> <p>20 vigorous than FDA, and there's at least one of them.</p> <p>21 But I think that I made a comment that</p> <p>22 there were more MHRA inspections.</p> <p>23 So there's -- I start to catalog</p> <p>24 inspection one, inspection two, inspection three,</p> <p>25 through the timeline, identify them as MHRA or FDA,</p>

21 (Pages 78 to 81)

Karen A. Frank, M.D.

Videotaped

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<p>1 identify the site, try to specify whether they were</p> <p>2 actually looking at the pharmacovigilance systems and</p> <p>3 then map out -- since I don't know what happened from</p> <p>4 the time the first consent decree was lifted to the</p> <p>5 first inspections to really put down the facts and</p> <p>6 start to build a picture of what happened, what</p> <p>7 failed, what was corrected, what was adequately</p> <p>8 corrected, what was inadequately corrected, and what</p> <p>9 was found on the repeat FDA inspection of 2008.</p> <p>10 The more that I can get an accurate</p> <p>11 assessment the course of events, it will allow an</p> <p>12 accurate assessment of what happened inside the</p> <p>13 company and any potential impact on signal detection</p> <p>14 for either Digitek or any of the other products that</p> <p>15 were dependent on those business processes during that</p> <p>16 period.</p> <p>17 Q. But you've already told us that there's</p> <p>18 a substantial amount of underlying company documents</p> <p>19 you have not looked at; correct? Correct?</p> <p>20 A. I have -- I'm going to have to say a</p> <p>21 simple yes.</p> <p>22 Q. Right. And then I wanted to get back to</p> <p>23 my original question.</p> <p>24 And I thank you for your answer.</p> <p>25 But my original question was how you</p>	<p>1 And I started to function more like a</p> <p>2 truth seeker. And I don't know how to completely</p> <p>3 explain.</p> <p>4 I'm extremely concerned that the</p> <p>5 information gathered in the assessment is accurate and</p> <p>6 complete and can reflect on the signal detection.</p> <p>7 And I spoke with them last night, and I</p> <p>8 will need to talk to Dr. Miller if you need me to give</p> <p>9 you further detail on my concerns.</p> <p>10 Q. But as you sit here, in spite of the</p> <p>11 questions --</p> <p>12 MR. KAPLAN: Mr. Miller? Did you say</p> <p>13 Dr. Miller?</p> <p>14 THE WITNESS: It's mister.</p> <p>15 MR. KAPLAN: Pete Miller; correct?</p> <p>16 THE WITNESS: No, I'm sorry.</p> <p>17 Mr. Thompson. Mr. Thompson.</p> <p>18 BY MR. DEAN:</p> <p>19 Q. So as of today, you have made your</p> <p>20 concerns about lack of information known to the</p> <p>21 plaintiffs' counsel and you've done that in the past.</p> <p>22 I understand that, too.</p> <p>23 But you did it again last night;</p> <p>24 correct?</p> <p>25 A. Yes.</p>
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<p>1 viewed your role as an expert witness, whether you</p> <p>2 viewed yourself as an advocate on behalf of the</p> <p>3 plaintiffs or whether you viewed yourself as an</p> <p>4 impartial observer relating comments about documents</p> <p>5 that you had reviewed.</p> <p>6 Which is -- which role do you see</p> <p>7 yourself in, Dr. Frank?</p> <p>8 MR. THOMPSON: Object to the form.</p> <p>9 BY MR. DEAN:</p> <p>10 Q. Go ahead.</p> <p>11 A. How do I respond to his objection?</p> <p>12 Q. He's made that for the record. You can</p> <p>13 go ahead and give your answer.</p> <p>14 A. Okay. I was hired by the plaintiffs to</p> <p>15 address very specific issues, to look how these</p> <p>16 systems potentially impacted signal detection during</p> <p>17 Digitek recall.</p> <p>18 I needed to do -- I'm going to use a</p> <p>19 legal term -- due diligence in the scope of work that</p> <p>20 they asked me to meet.</p> <p>21 In doing that, I became concerned about</p> <p>22 the completeness of the information that I was seeing</p> <p>23 and the fact that my opinion based on that information</p> <p>24 could be vulnerable if this information that I don't</p> <p>25 have was brought forward.</p>	<p>1 Q. And you have those concerns, as you sit</p> <p>2 here today, that you don't have a full and complete</p> <p>3 information base on which to give your opinion; is</p> <p>4 that correct?</p> <p>5 A. I am privy to some of the information</p> <p>6 that was obtained in due diligence on drug</p> <p>7 withdrawals. I'm talking market withdrawals, not</p> <p>8 recall of the lots.</p> <p>9 And the information obtained in the</p> <p>10 discovery of this case was not as extensive in those</p> <p>11 cases. And I started to ask about the discovery.</p> <p>12 Is this the discovery you would expect</p> <p>13 to see in a case like this or are the absence of the</p> <p>14 MHRA inspections? The absence of the company internal</p> <p>15 signal document, are those issues?</p> <p>16 But there apparently was not a further</p> <p>17 investigation done, and I was told not to start to</p> <p>18 talk into that direction.</p> <p>19 Q. As recently as last night, Dr. Frank,</p> <p>20 you expressed an opinion to the plaintiffs' counsel</p> <p>21 that you had inadequate information and concerns about</p> <p>22 the adequacy of the information to testify today; is</p> <p>23 that correct?</p> <p>24 A. Yes.</p> <p>25 Q. Okay. Now, you talked about the</p>

22 (Pages 82 to 85)

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<p>1 adequacy of signal detection. I want to, in the</p> <p>2 context of Digitek -- and you understand that product</p> <p>3 was recalled; correct?</p> <p>4 A. Yes.</p> <p>5 Q. In the context of Digitek, would -- let</p> <p>6 me strike that.</p> <p>7 Your -- one of your expertises is</p> <p>8 pharmacovigilance; correct?</p> <p>9 A. Yes. I've worked in the field for</p> <p>10 several years.</p> <p>11 Q. Correct.</p> <p>12 And, typically, in the field of</p> <p>13 pharmacovigilance, representatives of pharmaceutical</p> <p>14 companies are looking at a vast array of information</p> <p>15 to see if new and different adverse reactions are</p> <p>16 arising from their drugs.</p> <p>17 Is that a fair summary?</p> <p>18 A. Yes.</p> <p>19 Q. And in this case, you -- this case being</p> <p>20 the Digitek case, you understand that there is a</p> <p>21 question about a manufacturing defect in the product?</p> <p>22 You understand that, don't you?</p> <p>23 A. Yes.</p> <p>24 Q. And that is -- would you agree with me</p> <p>25 that's -- it's unusual to address a manufacturing</p>	<p>1 Q. Okay. And -- is there a qualifier? Is</p> <p>2 that, indeed, what you're looking for, what you would</p> <p>3 be looking for in terms of a manufacturing defect</p> <p>4 case?</p> <p>5 A. With product complaint cases, I was</p> <p>6 explaining to you that there are often routine Health</p> <p>7 Hazard Assessments where the pharmacovigilance</p> <p>8 physician receives work products from quality for the</p> <p>9 product complaint and the investigation and the</p> <p>10 analytics.</p> <p>11 And then there are Health Hazard</p> <p>12 Assessments done in realtime where the company</p> <p>13 pharmacovigilance database is data mined for any cases</p> <p>14 that could indicate that that manufacturing defect was</p> <p>15 leading to adverse events that were reported, either</p> <p>16 globally or particularly in the market of</p> <p>17 distribution.</p> <p>18 Some companies will look at the medical</p> <p>19 literature, and some companies will go as far as to</p> <p>20 data mine the AERS database in Washington, which has</p> <p>21 -- which contains all the MedWatch forms submitted to</p> <p>22 the FDA, or the WHO database in Uppsala, Sweden, that</p> <p>23 contains all of the CIOMS forms submitted to EMEA.</p> <p>24 But there is typically, for these</p> <p>25 manufacturing defects that may have gone to market, an</p>
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<p>1 defect through signal detection?</p> <p>2 I'm not saying it can't be done, but I'm</p> <p>3 saying it's not the usual thing you do in</p> <p>4 pharmacovigilance; is that correct?</p> <p>5 A. Classically, signal detection is looking</p> <p>6 for new events.</p> <p>7 Q. All right.</p> <p>8 A. But this clustering of cases where the</p> <p>9 FDA was concerned that they didn't see all of them,</p> <p>10 any clustering of single cases should alert them to a</p> <p>11 potential batch issue.</p> <p>12 It could be an issue with a site, but it</p> <p>13 also could be -- could map to an issue with a</p> <p>14 distributed batch.</p> <p>15 And that should have -- be covered by an</p> <p>16 SOP in the company that will require either a case</p> <p>17 series or some form of analysis for that cluster of</p> <p>18 events.</p> <p>19 Q. So what you are looking for, what you</p> <p>20 would be looking for here in terms of signal detection</p> <p>21 in a manufacturing defect case, is whether -- whether</p> <p>22 the MedWatch reports were providing information to the</p> <p>23 company that there might be a manufacturing defect;</p> <p>24 correct?</p> <p>25 A. Yes.</p>	<p>1 assessment of the extent of the exposure, what batches</p> <p>2 could have been affected, what is the market</p> <p>3 distribution of those batches, and then is there any</p> <p>4 evidence that there are adverse events that are</p> <p>5 resulting in response to the market exposure of those.</p> <p>6 Q. So one of the key things that you want</p> <p>7 to do is to look at the Adverse Event Reports to see</p> <p>8 if they suggest a defect in manufacture in affected</p> <p>9 batches; correct?</p> <p>10 A. Yes.</p> <p>11 Q. And the other thing you mentioned in</p> <p>12 your prior answer was product complaints.</p> <p>13 And so is it also fair to say that if</p> <p>14 one -- if a company was concerned about a</p> <p>15 manufacturing defect, they could look to their product</p> <p>16 complaints on returned product and see -- and make an</p> <p>17 inquiry to see whether those resulted in any adverse</p> <p>18 experience reports?</p> <p>19 Is that something that companies do?</p> <p>20 A. You are correct. The work products fed</p> <p>21 to pharmacovigilance usually contain an assessment of</p> <p>22 are there any similar product complaint reports. And</p> <p>23 that in turn determines the scope of the batches that</p> <p>24 are potentially affected.</p> <p>25 Q. I don't want to interrupt, but I do want</p>

23 (Pages 86 to 89)

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<p>1 to move this along.</p> <p>2 What you are looking for -- strike that.</p> <p>3 What many companies have is a process by</p> <p>4 which there's communication between the folks on the</p> <p>5 signal detection side and folks on the product</p> <p>6 complaint side where they exchange information to see</p> <p>7 if it can be useful to the other side; is that</p> <p>8 correct?</p> <p>9 A. Yes.</p> <p>10 Q. Is that -- now, did you review the</p> <p>11 deposition of Sarita Thapar?</p> <p>12 A. Yes.</p> <p>13 Q. Didn't she, indeed, say that Actavis had</p> <p>14 such a communication process?</p> <p>15 A. Yes.</p> <p>16 Q. You have not reviewed the product</p> <p>17 complaints on Digitek prior to the recall, have you?</p> <p>18 A. No.</p> <p>19 Q. You have not reviewed the MedWatch</p> <p>20 reports prior to the recall, have you?</p> <p>21 A. No.</p> <p>22 Q. So you don't know whether there were any</p> <p>23 MedWatch reports which even gave off a signal of a</p> <p>24 manufacturing defect, do you?</p> <p>25 A. I went --</p>	<p>1 you want to answer, but you didn't -- you did not --</p> <p>2 you could not form any opinion as to whether there was</p> <p>3 communication between the product complaint side and</p> <p>4 the signal detection side on Digitek as relates to a</p> <p>5 manufacturing defect because you were not provided</p> <p>6 with those records, were you?</p> <p>7 A. My opinion is not based on the records.</p> <p>8 When I inquired on the June 2nd meeting and expressed</p> <p>9 my concerns, I was not given enough to document that</p> <p>10 process.</p> <p>11 But I found in the FDA inspections of</p> <p>12 2008 specific statements they were upset about the</p> <p>13 lack of Health Hazard Assessments.</p> <p>14 So what I did in trying to assess</p> <p>15 whether there was an adequacy, realtime Health Hazard</p> <p>16 Assessments, because I was not -- I was not provided</p> <p>17 all of the information that you talked about, even on</p> <p>18 questioning.</p> <p>19 I said, the only thing that I can find</p> <p>20 that says that there is perhaps something in place,</p> <p>21 but not in use, was the FDA observation.</p> <p>22 And that's documented in here with my</p> <p>23 comment about concern of lack of ongoing Health Hazard</p> <p>24 Assessments.</p> <p>25 Q. And that's the opinion of one</p>
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<p>1 Q. Would you answer that question, please.</p> <p>2 A. The answer is no.</p> <p>3 Q. And you don't know whether there were</p> <p>4 any product complaints prior to the recall that</p> <p>5 suggested there was a manufacturing defect, do you?</p> <p>6 A. I do know about the one from 2004 that</p> <p>7 led to an investigation. I did not receive the Health</p> <p>8 Hazard Assessment in association with that 2004</p> <p>9 investigation.</p> <p>10 Q. Beyond that 2004 incident, which you've</p> <p>11 talked -- which you just mentioned, have you reviewed</p> <p>12 any product complaints about Digitek prior to the</p> <p>13 recall?</p> <p>14 A. No. I believe all the ones I saw were</p> <p>15 post.</p> <p>16 Q. So -- right.</p> <p>17 So you don't know whether there was --</p> <p>18 at the end of the day, you don't know whether there</p> <p>19 was anything as to Digitek and the manufacturing</p> <p>20 defect with Digitek to be communicated between the</p> <p>21 product complaint section and the signal detection</p> <p>22 section, do you?</p> <p>23 A. I went looking to assess what was done,</p> <p>24 and I couldn't find anything. And then --</p> <p>25 Q. Could you -- I'll let you answer however</p>	<p>1 investigator; correct?</p> <p>2 A. And I --</p> <p>3 Q. Is that correct?</p> <p>4 MR. THOMPSON: Object to the form.</p> <p>5 BY MR. DEAN:</p> <p>6 Q. What you just referenced is the opinion</p> <p>7 of one investigator; correct?</p> <p>8 A. Possibly two, but, yes, one. It's one</p> <p>9 inspection, probably one investigator, possibly two.</p> <p>10 Q. Let me go back. Let me go back. And I</p> <p>11 want to get an answer to my other question, just so</p> <p>12 we're clear.</p> <p>13 You do not have an opinion as to the</p> <p>14 actual -- strike that.</p> <p>15 You have not had an opportunity to</p> <p>16 review the information exchanged between -- gathered</p> <p>17 by the product complaint section and the signal</p> <p>18 detection section as to -- as to the possibility of</p> <p>19 manufacturing -- strike that.</p> <p>20 You have not reviewed the information</p> <p>21 obtained by the product complaint section and the</p> <p>22 signal detection section prior to the time of the</p> <p>23 recall to determine the adequacy of the information</p> <p>24 exchanged between the two groups, have you?</p> <p>25 A. I have concern that there is an absence</p>

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<p>1 of information provided to me at this point in time on</p> <p>2 which I can base an opinion.</p> <p>3 Q. You haven't reviewed that information at</p> <p>4 this point, have you?</p> <p>5 A. No.</p> <p>6 Q. Correct? Is that correct?</p> <p>7 A. The information that I --</p> <p>8 MR. KAPLAN: Is that correct?</p> <p>9 THE WITNESS: No, I have not been</p> <p>10 provided that information.</p> <p>11 BY MR. DEAN:</p> <p>12 Q. Thank you.</p> <p>13 Could you tell us, and I don't want to</p> <p>14 -- I hope we don't spend much time on this, but I</p> <p>15 would just like for you to give us a brief overview of</p> <p>16 your job duties at the FDA, what you did when you were</p> <p>17 at the FDA.</p> <p>18 Could you do that for us, please?</p> <p>19 A. I spent two years at the FDA as a fellow</p> <p>20 in the division of cardio-renal drug products.</p> <p>21 And when I finished my fellowship, I was</p> <p>22 brought on as a GS-14 expert level reviewer in anti-</p> <p>23 infectives for the small molecules for sepsis and</p> <p>24 septic shock that had been moved from cardio-renal to</p> <p>25 anti-infectives.</p>	<p>1 to class black box labelings, and they put together a</p> <p>2 labeling review and sent it in to the FDA, and I was</p> <p>3 assigned it and I started on it.</p> <p>4 Q. Let me interrupt and see if I can speed</p> <p>5 this along.</p> <p>6 Would it be fair to say that when you</p> <p>7 were at the FDA, you basically did medical review of</p> <p>8 INDs, NDAs, and addressed labeling issues?</p> <p>9 Is that a fair summary?</p> <p>10 MR. THOMPSON: Object to the form.</p> <p>11 THE WITNESS: I did. I also did some</p> <p>12 review of --</p> <p>13 BY MR. DEAN:</p> <p>14 Q. Just give me the other broad areas that</p> <p>15 you might -- I don't need the detail, but just a broad</p> <p>16 area.</p> <p>17 A. I did some peer review of -- or I did</p> <p>18 some review of peer-reviewed literature that came into</p> <p>19 the FDA for FDA review prior to publication, because</p> <p>20 there had been disputes between peer-reviewed</p> <p>21 publications and the FDA in that the peer-reviewed</p> <p>22 publications were talking too much about off-label</p> <p>23 use.</p> <p>24 Q. Okay. Go ahead. Anything else?</p> <p>25 A. I assisted on the placebo hypertension</p>
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<p>1 They needed cardiovascular expertise.</p> <p>2 I also reviewed things in anti-infective</p> <p>3 products. I --</p> <p>4 Q. When you say "reviewed things," what</p> <p>5 were you doing?</p> <p>6 A. I did IND reviews.</p> <p>7 Q. Okay.</p> <p>8 A. NDA reviews. I did updated class</p> <p>9 labeling.</p> <p>10 There was a -- an innovative product</p> <p>11 that had been lax in updating their drug label, and a</p> <p>12 me-too drug came along, and they approached the FDA</p> <p>13 about leveling the playing field for competitive</p> <p>14 marketing by forcing the innovator to update their</p> <p>15 drug label.</p> <p>16 And I was the person who wrote the</p> <p>17 initial draft of the updated drug label based on all</p> <p>18 information on the two drugs. And I provided that to</p> <p>19 FDA supervisory.</p> <p>20 I then received -- I also did a workup</p> <p>21 on an FDA advisory panel recommendation for black box</p> <p>22 warnings on a class of drug for antimicrobial</p> <p>23 resistance.</p> <p>24 And one of the companies decided to</p> <p>25 challenge the fact that their drug should be subjected</p>	<p>1 project where they pooled placebo data on hypertension</p> <p>2 trials to justify the use of placebo groups in short-</p> <p>3 term Phase II trials demonstrating pharmacodynamic</p> <p>4 efficacy of hypertensive agents.</p> <p>5 Q. At any time when you were with the FDA,</p> <p>6 did you do an inspection of a manufacturing facility?</p> <p>7 A. No. I was not in the -- in that</p> <p>8 office. I was in the review divisions.</p> <p>9 Q. All right. Now, would I also -- from my</p> <p>10 review of your resume, you are not an expert on</p> <p>11 manufacturing of drugs, are you?</p> <p>12 A. No.</p> <p>13 Q. You are not an expert on quality control</p> <p>14 procedures in regard to the manufacturing of drugs,</p> <p>15 are you?</p> <p>16 A. No.</p> <p>17 Q. You are not an expert on quality</p> <p>18 assurance issues in regard to the manufacturing of</p> <p>19 drugs, are you?</p> <p>20 A. No.</p> <p>21 Q. Okay. Have you -- when you were with</p> <p>22 the FDA, did you have any experience with recalls?</p> <p>23 A. FDA, not that I'm aware of. The only</p> <p>24 thing that I recall are clinical holds on clinical</p> <p>25 trials.</p>

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<p>1 Q. When you were in --</p> <p>2 A. There was -- I was made aware of that,</p> <p>3 but I was not involved with it. I take that back.</p> <p>4 Q. I know that you have a work history in</p> <p>5 private industry as well.</p> <p>6 During your time in private industry,</p> <p>7 did have any experience with pharmaceutical recalls?</p> <p>8 A. I did not implement the recalls. I did</p> <p>9 the Health Hazard Assessments for them.</p> <p>10 Q. So that would -- the extent of your</p> <p>11 involvement with a recall would be to do the Health</p> <p>12 Hazard Evaluation; correct?</p> <p>13 A. Yes.</p> <p>14 Q. Okay. Isn't it true that the FDA can</p> <p>15 ask that a product be recalled for any reason?</p> <p>16 A. I will say yes.</p> <p>17 Q. Okay. And there is no legal requirement</p> <p>18 that a product be defective before it's subject to a</p> <p>19 recall, is there?</p> <p>20 A. I do not know the answer to that</p> <p>21 question. I cannot think of that -- where that is</p> <p>22 stipulated in the CFR.</p> <p>23 Q. Has any company that you've ever worked</p> <p>24 for received a 483?</p> <p>25 A. Yes.</p>	<p>1 A. Yes.</p> <p>2 Q. Okay. So you do have some knowledge on</p> <p>3 that, don't you?</p> <p>4 A. Yes.</p> <p>5 Q. And you would agree with me that the 483</p> <p>6 form itself says it's not a final agency action;</p> <p>7 correct?</p> <p>8 A. Yes.</p> <p>9 Q. I take it, you're not -- going from your</p> <p>10 report, you're not going to testify about issues of</p> <p>11 adulteration; is that correct?</p> <p>12 A. No. They've asked me to be very</p> <p>13 specific in testifying on issues of these systems and</p> <p>14 not to go out of scope into issues that would be</p> <p>15 covered by the cardiologists.</p> <p>16 Q. Well, just so I'm clear, you're not</p> <p>17 going to say that because a drug is adulterated, it's</p> <p>18 defective? You're not going to offer an opinion like</p> <p>19 that, are you?</p> <p>20 A. No.</p> <p>21 Q. Okay. And you're not going to be</p> <p>22 offering any medical opinions on individual cases;</p> <p>23 correct?</p> <p>24 A. No.</p> <p>25 Q. I'm correct, you're not?</p>
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<p>1 Q. Has any company you've ever worked for</p> <p>2 received a warning letter?</p> <p>3 A. Yes.</p> <p>4 May I ask a clarifying question?</p> <p>5 Q. No.</p> <p>6 A. Okay.</p> <p>7 Q. What is a 483?</p> <p>8 A. A 483 is an FDA form in which the</p> <p>9 inspectors report their initial observations of the</p> <p>10 inspection.</p> <p>11 Q. Is it a final agency action?</p> <p>12 A. It is taken back into the FDA and it</p> <p>13 produces a warning letter.</p> <p>14 Q. Is it a final agency action?</p> <p>15 A. I do not know the answer to that</p> <p>16 question. In legal terms, if it's -- if it -- what</p> <p>17 constitutes a final agency action. I never --</p> <p>18 Q. Did you review any of the 483s in this</p> <p>19 case?</p> <p>20 A. Yes.</p> <p>21 Q. Did you -- do you have any recollection</p> <p>22 of observing on the 483s whether it speaks to that</p> <p>23 issue that I just asked you about?</p> <p>24 A. Yes. It says that it is not a final.</p> <p>25 Q. Does it -- do you remember that?</p>	<p>1 A. Correct. I am not.</p> <p>2 Q. Okay. Thank you.</p> <p>3 Would you agree that if the FDA, in its</p> <p>4 dealings with a company, has concerns about data</p> <p>5 integrity, it will take aggressive action vis-a-vis</p> <p>6 that company?</p> <p>7 MR. THOMPSON: Object to the form.</p> <p>8 THE WITNESS: Please repeat the</p> <p>9 question.</p> <p>10 BY MR. DEAN:</p> <p>11 Q. In your experience, if the FDA has</p> <p>12 questions about data integrity within a company, will</p> <p>13 it take aggressive actions to follow up with that</p> <p>14 company?</p> <p>15 A. Yes.</p> <p>16 Q. In your review of the documents you've</p> <p>17 been provided, you didn't see any indication that the</p> <p>18 FDA had any such concerns; correct?</p> <p>19 A. There were no explicit statements on</p> <p>20 data integrity. There were, however, inspection</p> <p>21 observations of inaccuracies and incompleteness of</p> <p>22 narratives and coding on MedWatch forms.</p> <p>23 Incomplete coding on MedWatch forms can</p> <p>24 mean incomplete data retrieval on case series and</p> <p>25 aggregate signal detection.</p>

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1 I have not seen any coding conventions
2 from Actavis, and I have not seen any primary
3 documents that would allow me to make any further
4 statement of the impact of coding issues on signal
5 detection.

6 But the FDA inspector's observation
7 raised concerns about quality issues in the safety
8 database, coding and the case retrieval for signal
9 detection. I can't comment on the extent.

10 Q. Would you agree that in the context of
11 the AERs that you're testing -- testifying about, the
12 FDA never raised a specific question in regard to data
13 integrity?

14 Do you agree with that?

15 A. That term was not in any of the
16 documents that I reviewed.

17 Q. Do you have any knowledge as to whether
18 a double-thick tablet of Digitek ever reached the
19 market?

20 Do you have any specific knowledge of
21 that?

22 A. The only evidence I have that a double-
23 thick tablet reached the market is the 2004 inspection
24 report where a double-thick tablet was returned to the
25 company from a pharmacist in Bellingham, Washington.

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1 I cannot recall from the product
2 complaints that I reviewed if there's specific
3 evidence in those. I would have to re-review them and
4 report back to you.

5 But I have no MedWatches, CIOMS forms,
6 or aggregate reports, or any information on the recall
7 product that was incinerated, that would allow me to
8 make any assessment of how many or the percentage of
9 any batch of double-thick tablets that reached the
10 markets.

11 Q. Is the only one that you are aware of
12 the one you referenced in 2004?

13 A. There has been reference to a 2008, but
14 I cannot recall that I was provided any documents on
15 that case in 2008.

16 Q. Do you know whether -- what's your
17 understanding as to double-thick tablets in 2008, if
18 you have any?

19 A. Something was mentioned this morning.
20 But what I have are the inspection reports and the
21 recall package to finding the batches at risk.

22 I cannot picture in any documents sent
23 to me any sentence that says X tablet reached the
24 market, X tablet was ingested by a patient or X tablet
25 was returned to the company.

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1 Q. Is the only information that you would
2 have in response to my question what would be
3 contained in an FDA document? Is that fair?

4 A. Unless there is something in -- I was
5 sent sample product complaints toward the end, and I
6 did not loop them in as evidence. They are on the
7 flash drive.

8 I cannot recall any specifics right now
9 of those. But there may be on those product
10 complaints statements that I do not recall about
11 double-thick tablets. I cannot recall them.

12 So I have to say no. The only thing
13 that I am absolutely certain that I have seen is 2004.

14 Q. Okay. And let me ask you a few follow-
15 up questions in regard to that.

16 MR. DEAN: Why don't we go off the
17 record for just a minute while I find this document.

18 VIDEO OPERATOR: Going off the video
19 record.

20 The time is 11:38 a.m.

21 (Discussion off the record.)

22 VIDEO OPERATOR: We're now back on the
23 video record.

24 The time is 11:40 a.m.

25 BY MR. DEAN:

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1 Q. In your report, which we marked, you
2 reference that 2004 --

3 A. Yes.

4 Q. -- double thick observation. But you
5 did not reference any follow-up by the FDA.

6 Did you inquire as to the plaintiffs'
7 lawyers whether the FDA itself did any follow-up on
8 the 2004 double thick observation?

9 A. No.

10 Q. Do you know whether the company reported
11 it to the FDA?

12 A. No.

13 Q. Would you have expected the company to
14 report it to the FDA?

15 A. I'm going to say yes, it should have
16 generated a field alert. But I must qualify that,
17 that it's not my area of expertise.

18 Q. Would this -- would the FDA follow --
19 would the possibility of an FDA follow-up to this 2004
20 observation be within one of the white spaces you
21 mentioned before?

22 A. Yes.

23 Q. Let me show you Exhibit 20. And I'm
24 going to -- eventually I'm going to direct your
25 attention to a specific page, but generally do you

27 (Pages 102 to 105)

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<p>1 recognize what kind of a document this is?</p> <p>2 A. This is an inspection. It's a CGMP</p> <p>3 inspection.</p> <p>4 Q. And was it prepared by -- it was</p> <p>5 prepared by the FDA; correct?</p> <p>6 Look at the back of it.</p> <p>7 A. Yes.</p> <p>8 Q. And on the front page, on the bottom</p> <p>9 under Administrative Procedures, it says, We,</p> <p>10 Investigators Erin McCaffrey and Robert Horan, issued</p> <p>11 a 482 Notice of Inspection; correct?</p> <p>12 A. Yes.</p> <p>13 Q. So this is the FDA inspectors inspecting</p> <p>14 Actavis in 2004; correct?</p> <p>15 A. Yes.</p> <p>16 Q. In December of 2004; correct?</p> <p>17 A. 12/1/04, yes.</p> <p>18 Q. Okay. Now, let me direct you -- your</p> <p>19 attention to Page 6 of this report.</p> <p>20 Do you see where it says, Field Alert</p> <p>21 Reporting?</p> <p>22 A. Yes.</p> <p>23 Q. Before I ask you the next series of</p> <p>24 questions, could you just take a minute and read that</p> <p>25 paragraph, please.</p>	<p>1 A. Yes.</p> <p>2 Q. And then it says, corrective actions</p> <p>3 were verified during the inspection; correct?</p> <p>4 A. Yes.</p> <p>5 Q. And you have no reason to disagree with</p> <p>6 any of the conclusions reached by the FDA in this</p> <p>7 Field Alert in regard to the 2004 double thick</p> <p>8 observation, do you?</p> <p>9 A. No.</p> <p>10 Q. Okay. Now, is this the kind of document</p> <p>11 that you would have liked to have seen when you were</p> <p>12 compiling your report, at least a part of it, in</p> <p>13 regard to the 2004 double thick issue?</p> <p>14 A. Yes. It would have assisted in this</p> <p>15 timeline, and of documenting corrective actions and</p> <p>16 adequacy of corrective actions over this period.</p> <p>17 Q. Because that's one thing you're looking</p> <p>18 for; right?</p> <p>19 A. Yes.</p> <p>20 Q. And here they did -- Actavis did exactly</p> <p>21 that, they reported it, they took corrective actions,</p> <p>22 and the FDA was satisfied with those corrective</p> <p>23 actions; correct?</p> <p>24 A. Yes. In December of 2001, it is clearly</p> <p>25 documented --</p>
Page 107	Page 109
<p>1 A. Yes.</p> <p>2 (Witness reviews document.) Okay.</p> <p>3 Q. So, first of all, we can agree that the</p> <p>4 -- in the first two sentences it says that the -- a</p> <p>5 Field Alert was issued and it was submitted to the New</p> <p>6 Jersey District Office; correct?</p> <p>7 A. Yes.</p> <p>8 Q. So Actavis submitted this as a Field</p> <p>9 Alert to the District Office; correct?</p> <p>10 A. Uh-huh.</p> <p>11 Q. Yes?</p> <p>12 A. Yes.</p> <p>13 Q. And then the FDA, when they were there</p> <p>14 during this inspection, did follow-up on that;</p> <p>15 correct?</p> <p>16 A. Yes.</p> <p>17 Q. And the FDA noted that, besides this one</p> <p>18 tablet, no additional complaints or reports of thick</p> <p>19 tablets have been received for this high-volume</p> <p>20 product; correct?</p> <p>21 A. Yes.</p> <p>22 Q. And they further concluded the event was</p> <p>23 considered an isolated incident and corrective actions</p> <p>24 were put in place to prevent its reoccurrence;</p> <p>25 correct?</p>	<p>1 Q. I'm sorry, December 2004.</p> <p>2 A. 2004. In December 2004, this document</p> <p>3 clearly states that the Field Alert was issued. There</p> <p>4 was inspection follow-up.</p> <p>5 My reading of this paragraph includes</p> <p>6 that the FDA is actually confirming some of the</p> <p>7 conclusions of the report that I received. We can</p> <p>8 verify that point by point if we need to.</p> <p>9 And they are saying at that time they</p> <p>10 consider the corrective actions to be verified. And</p> <p>11 my assumption is verification means adequate.</p> <p>12 Q. Okay. Thank you. Let me get that out</p> <p>13 of your way.</p> <p>14 Have you ever taught or published about</p> <p>15 pharmacovigilance?</p> <p>16 A. I gave internal seminars inside CSC.</p> <p>17 Q. Inside what?</p> <p>18 A. Inside one of the consulting firms that</p> <p>19 I worked for. The -- they had approached me about</p> <p>20 talking at national conventions, but I did not. And,</p> <p>21 no, I have no publications on pharmacovigilance.</p> <p>22 Q. And you've never taught in -- outside of</p> <p>23 the context in which you just mentioned; right?</p> <p>24 A. No. I have never done independent</p> <p>25 workshops, and I cannot recall ever having done the</p>

28 (Pages 106 to 109)

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1 official company SOP training on pharmacovigilance.
 2 Q. Now, can we agree that MedWatch reports
 3 -- the information in MedWatch reports that's received
 4 does not mean that a drug caused a specific adverse
 5 event that may be described in the report?
 6 A. Yes.
 7 Q. It doesn't even try to do that, does
 8 it? A MedWatch report does not even attempt to do
 9 that; correct?
 10 A. The MedWatch form does not, but the
 11 CIOMS reports contain CIOMS comments.
 12 So in the database, there can be CIOMS
 13 comments that will map if the database prints to a
 14 CIOMS form, and I do not believe they will map to the
 15 FDA 3500, the MedWatch.
 16 But there can be assessments of
 17 reporters and company on the MedWatch and the CIOMS,
 18 and CIOMS companies assessing all of that information
 19 in light of the narrative on the CIOMS and in the
 20 database.
 21 Because one of the very important things
 22 in a company when you have the databases, there is a
 23 reporter's field for causality or relatedness --
 24 relatedness, and there's a company field.
 25 And you want those two to be in parallel

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1 and transparent.
 2 Occasionally you hear stories of
 3 companies who say we only need one field and the
 4 company can overwrite the reporters.
 5 But it is extremely important to
 6 maintain two transparent fields with a reporter
 7 assessment of relatedness, a company assessment of
 8 relatedness.
 9 The company assessment of relatedness
 10 may be based on a probabilistic analysis, such as the
 11 Naranjo algorithm, and all of that is typically put
 12 into a CIOMS comment that also resides in the
 13 database.
 14 Q. Let's go back. First of all, a MedWatch
 15 report itself does not even attempt to get at the
 16 issue of causation; correct?
 17 A. Yes.
 18 Q. Now, you mentioned a CIOMS report. I
 19 want to ask you about that. I -- in one of my past
 20 lives, I actually knew what those initials stood for,
 21 but you're going to have to refresh my recollection.
 22 If you first give me the initials and
 23 then tell me what they stand for.
 24 A. I think it was my past lifetime, too.
 25 Q. First, do you remember the initials?

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1 And if you don't, that's fine.
 2 A. No. It's a working committee within the
 3 WHO that repeatedly analyzes pharmacovigilance
 4 practices and publishes recommendations that are
 5 available through the WHO in Geneva, but I'm blanking
 6 on the actual acronym.
 7 Q. And that's fine. So --
 8 MR. KAPLAN: I think it's S-C-I-O-M-S.
 9 THE WITNESS: It's C-I-O-M-S.
 10 MR. KAPLAN: It's S-C.
 11 THE WITNESS: It's C. Charlie, Ingrid,
 12 Oliver, Mark, Sam.
 13 MR. KAPLAN: See what I know? Not very
 14 much.
 15 BY MR. DEAN:
 16 Q. And is this a group that takes a number
 17 of MedWatches and tries to analyze or synthesize them
 18 and issue a report?
 19 What is it that they do? I wasn't quite
 20 sure what you were saying that they did.
 21 A. No. They actually do higher level work
 22 that actually translates into recommended --
 23 recommendations for best practices in
 24 pharmacovigilance.
 25 Q. But they don't take an individual

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1 MedWatch report and try to tease out causality from an
 2 individual MedWatch report, do they?
 3 A. No. But the CIOMS form is the XUS
 4 equivalent of the FDA 3500.
 5 Q. Okay.
 6 A. And when these databases are
 7 constructed, the fields are in the databases and
 8 there's -- there's a menu that allows the company to
 9 print out the FDA form, the CIOMS form for the EMEA,
 10 the specific form that goes to the BfArM in Germany,
 11 on and on and on.
 12 The same fields in the databases are
 13 mapping to country-specific forms. They can submit
 14 the CIOMS form to the FDA in lieu of the 483.
 15 Q. In lieu of the AER?
 16 A. In lieu of the MedWatch --
 17 Q. Right.
 18 A. -- 350.
 19 Q. Yes.
 20 A. So there are companies that don't do
 21 CIOMS comments because they just submit 350s.
 22 Q. But if a company was to submit the CIOMS
 23 report as opposed to the MedWatch 350, that would
 24 contain basically the same information that's on the
 25 MedWatch, just on another form; correct?

29 (Pages 110 to 113)

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1 A. Yes. Now --

2 Q. Is that correct?

3 A. Yes.

4 Q. And then if it -- so if it contains the
5 same information, it would not attempt to get at
6 causality, either, would it?7 A. They do not have a hundred percent
8 concordance.9 The CIOMS forms contain CIOMS comments,
10 which are typically a statement of causality, based on
11 the reporter's causality, the medical judgment on the
12 narrative, plus or minus a quantitative probabilistic
13 algorithm on causality, such as the Naranjo.14 Q. But you have a number of reviewers that
15 are looking at a particular report; correct?16 A. Yes. And there could be discordance in
17 their assessments. And that's why I made the point of
18 the importance of the transparency of the reporter's
19 assessment of causality and the company's assessment
20 of causality.21 Those are to be considered independent
22 and recorded in parallel and transparent. And if the
23 company wishes to refute the reporter, they can do so,
24 but they cannot overwrite or obliterate the reporter's
25 causality.

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1 Q. Do you have any evidence -- for the
2 purposes of this question, I want to put aside the
3 double thick issue.

4 A. Okay.

5 Q. Do you have any evidence that any normal
6 size Digitek tablet reached the market which was out
7 of specification prior to the time of the recall?

8 A. No.

9 Q. Okay. Do you -- are you aware that --
10 are you aware of something called an FDA 484?

11 A. Would you clarify?

12 Q. Are you aware that sometimes the FDA
13 will, unbeknownst to a particular company, go out and
14 obtain product from the market and test it to see if
15 it meets specifications?16 A. I have heard of that procedure. I have
17 not been formally trained on it, nor have I been
18 formally involved in it. And I was not the recipient
19 of the reports from that procedure when I was at the
20 FDA.21 Q. Have you been informed in this case that
22 the FDA indeed went out and tested Digitek that was on
23 the market prior to the time of the recall?24 A. No. I have not been informed verbally
25 or in writing.

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1 Q. Have you been informed that a company
2 called UDL did -- I'm sorry.3 Have you been informed that a company
4 called Celsius did testing on Digitek that was on the
5 market prior to the time of the recall?6 A. No. However, I did not, nor did I ask
7 for this. My assumption is that these documents would
8 have routed to an expert witness who was actually
9 expert in that area.10 Q. And that's outside your area of
11 expertise, product -- product manufacture and testing;
12 correct?

13 A. Yes.

14 Q. Did either Mr. Miller, Ms. Johnson or
15 Mr. Thompson tell you that the plaintiffs' lawyers in
16 this litigation had publicly abandoned the theory of
17 double-thick tablets?

18 A. No.

19 Q. Would that surprise you to learn about
20 that?21 MR. THOMPSON: Object to the form.
22 BY MR. DEAN:23 Q. Would it surprise you to know that
24 Mr. Thompson has filed papers with the court that says
25 the whole issue of double-thick tablets is a red

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1 herring?

2 MR. THOMPSON: Object to the form.

3 THE WITNESS: I was not informed of
4 that. I -- I was aware that they were going to pursue
5 the batch uniformity issue, but I was not aware the
6 double-thick tablet issue had been abandoned.

7 BY MR. DEAN:

8 Q. Would you have bothered to put any
9 reference to double-thick tablets in your report if
10 you had known that the theory had been abandoned and
11 that plaintiffs were referring to it as a red herring?

12 MR. THOMPSON: Object to the form.

13 THE WITNESS: No.

14 I was asked specifically to evaluate the
15 systems and the impact on the signal detection in the
16 Digitek case, and they were discussing the double-
17 thick tablet and the blend issue, but I was not told
18 the double-thick tablet had been abandoned.19 I was not shown the FDA press release
20 stating that there was no risk to public health in the
21 Digitek recall. And I have no information that allows
22 me to quantify the statistical probability of the
23 impact of the blend issue.24 These were maintained as abstract risks,
25 and most of the information that I would have needed

30 (Pages 114 to 117)

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<p style="text-align: right;">Page 118</p> <p>1 to determine any probability was redacted out of what 2 I received. 3 In other words, how many tablets were 4 actually in a batch, what was the likelihood that 5 those batches -- those tablets all ended up in one 6 bottle and ingested by one patient or evenly 7 distributed throughout a -- throughout bottles, one 8 tablet per bottle, which is a different risk. 9 One double-thick tablet in a bottle is 10 the medical equivalent of a patient accidentally 11 taking a double daily dose. 12 BY MR. DEAN: 13 Q. Would you -- 14 A. I have no information on these 15 statistical probabilities or on either plaintiffs' or 16 defendants' assessment of those issues. 17 Q. Would you agree it would be a waste of 18 time to do signal detection for something that is 19 admittedly a red herring? 20 MR. THOMPSON: Object to the form. 21 THE WITNESS: When was it determined to 22 be a red herring? 23 BY MR. DEAN: 24 Q. Well, sometime within the last year. 25 A. If, indeed, it was a red herring, I</p>	<p style="text-align: right;">Page 120</p> <p>1 Q. And when you say that, establish a risk 2 from double thick or a blend issue, you don't mean by 3 looking at manufacturing records, you mean by looking 4 at records within your area of expertise; right? 5 A. Well, as an FDA medical reviewer, we 6 have classes on a lot of this. We don't become 7 expert. But I started to ask questions of the risk of 8 population exposure. Is this one tablet per batch or 9 is it 50 percent of the batch? 10 There were -- and I'm not an expert on 11 this, but they did a visual inspection of a batch of 12 3.4 million tablets and pulled out a couple dozen. 13 I have no idea -- I'm starting to say, 14 what's the risk to a patient population of what the 15 percentage of that batch was that could have 16 potentially been double thick? 17 Because, to my assessment, the entire 18 batch was not submitted to a validated screening for 19 those double-thick tablets. 20 Q. You already admitted that you're not an 21 expert in quality assurance or quality control; 22 correct? 23 A. Yes, but I would have liked them to have 24 sent me something that was quantitative. But there 25 was nothing.</p>
<p style="text-align: right;">Page 119</p> <p>1 would agree with you. But the -- there is generally a 2 compulsive nature -- there is generally a compulsive 3 nature to evaluating potential risk. 4 I have no information on potential 5 versus actual risk, and I do not know at which time 6 potential risk was abandoned. 7 The investigation of the double-thick 8 tablet from 2004 did not include analytics to allow 9 assessment of suprapotency or subpotent dose of 10 Digoxin. I was also not provided the routine Health 11 Hazard Assessment with that finding. 12 And let me be careful with this one, 13 I've been trying to assess over the course of this 14 period if there's documentation of recurrence, what 15 percentage of the batch, how is it distributed into 16 the bottles, and all of that information has not been 17 provided to me. 18 I cannot say based on what's been 19 provided to me that there was no risk. 20 I -- I really need to be very careful 21 because there's -- there's an absence of information 22 provided to me to be -- that I can independently 23 substantiate the risk of the double-thick tablets or 24 the blend issue, the period of time associated with 25 the risk or the magnitude of the risk.</p>	<p style="text-align: right;">Page 121</p> <p>1 Q. So you have an absence of information on 2 that issue; correct? 3 A. Yes. 4 MR. DEAN: Okay. Our videotape is 5 almost expired. 6 Let's go off the record. 7 VIDEO OPERATOR: Going off the video 8 record. 9 This is the end of Tape 2. 10 The time is 12:03 p.m. 11 (A luncheon recess was taken from 12 12:03 p.m. to 1:05 p.m.) 13 VIDEO OPERATOR: We're now back on the 14 video record. 15 This is the start of Tape 3. 16 The time is 1:05 p.m. 17 BY MR. DEAN: 18 Q. You understand you're still under oath, 19 Dr. Frank? 20 A. Yes. 21 Q. Dr. Frank, do you understand that the -- 22 that in this litigation a number of people are trying 23 to recover money as the result of the injuries they 24 allege they received from taking Digitek tablets? 25 Do you understand that to be the</p>

31 (Pages 118 to 121)

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1 underlying purpose of the litigation?

2 A. Yes.

3 Q. Okay. And do you understand -- do you

4 have an understanding as to whether the FDA has spoken

5 on the issue of whether there was likely harm to

6 consumers from Digitek?

7 A. Last night, Mr. Thompson read the press

8 release to me. I am not privy to the FDA procedures

9 or the extent of the data mining that went on in order

10 to support that statement that there was no risk to

11 public health.

12 My assumption, having been in the FDA,

13 is that that statement would have been based on all of

14 the existing available data at that time.

15 But having never worked in that division

16 of the FDA and having not been exposed to those

17 procedures, I cannot comment any further than to say I

18 was read that press release.

19 Q. Was that -- the answer you just gave me,

20 was that the answer that you were instructed to give

21 last night by the plaintiff's counsel?

22 A. No. In fact, I brought it up. And they

23 had asked me to be extremely cautious probing into

24 data mining issues.

25 Q. Did you -- was that your first notice

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1 about that FDA statement, last night?

2 A. Yes. I was kept relatively agnostic as

3 to the present assessment of the actual risk.

4 Most -- I think that's why I'm somewhat

5 -- I'll use the word "anxious" about my opinions

6 because I've been looking at systems for potential of

7 risk that I've not seen any data that I can

8 independently assess.

9 And I'm looking at systems where I know

10 what probably the industry standard would be to

11 document due diligence in assessing risk.

12 And so I'm responding on FDA

13 observations in the absence of some of the supporting

14 data. And having been provided very little data on

15 the actual risk.

16 So the fact that you are repeatedly

17 presenting me with new information, I expected. I am

18 concentrating on reacting as analytically as I can and

19 as accurately I can in responding as you present me

20 with this new information.

21 Q. Now, at any point during your work on

22 behalf of the plaintiffs, did you do any independent

23 research yourself on Digitek?

24 A. No. I was tempted to look at the

25 Congressional investigation, I was tempted to do a

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1 Google search, I was tempted to search the FDA web

2 site. I did not.

3 I left no Internet footprint of my

4 involvement in this case, other than the e-mail trail

5 that the Miller firm and Motley Rice left.

6 Q. So you did no independent research on

7 your own, outside of that which you were provided, by

8 the plaintiffs' counsel; correct?

9 A. No. I left nothing on the Google

10 server.

11 Q. And so let me hand you -- we've been

12 talking about the FDA statement. It's what we marked

13 as Plaintiff's Exhibit 38; correct?

14 A. Yes.

15 Q. And this was issued in July of 2009;

16 correct?

17 A. Yes.

18 Q. And so this would have been available

19 for -- to you if you had done what you refer to as a

20 Google search. If you had wanted to find this

21 document, you could have easily found it. It's on the

22 FDA web site; correct?

23 A. Yes. But given the privacy issues of

24 the Google server, I did not do any research on

25 Google.

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1 Q. Given the privacy issues?

2 A. I watch commentary TV occasionally, and

3 I was as affected by one particular documentary on

4 Google that aired in the last few months.

5 Q. I don't understand the answer. What do

6 you mean?

7 A. Well, you're asking me if I did an

8 independent search for this.

9 Q. Right.

10 A. I could have done it, and if I had been

11 instructed to do it, I would have done it. But if I

12 do a search on Google, I leave a footprint.

13 And right now you probably know enough

14 about the privacy issues surrounding the aggregate

15 data on these search engines.

16 So if I'm an expert witness and I'm

17 going out looking for information, I'm creating an

18 electronic trail that right now the legal community is

19 questioning the privacy issues on that server.

20 So I specifically maintained silence

21 unless I was instructed to go out and do so.

22 Am I making sense?

23 Q. I don't understand your answer, but I'm

24 not sure that's important.

25 A. Every search that I do on Google is

32 (Pages 122 to 125)

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<p>1 there for eternity and they data mine that aggregate</p> <p>2 data.</p> <p>3 Q. Who does?</p> <p>4 A. Google.</p> <p>5 Q. And what will they do with -- you were</p> <p>6 afraid of what Google would do with it if you did an</p> <p>7 Internet search? Is that what you're telling me?</p> <p>8 A. People can come to Google and get that</p> <p>9 data right now.</p> <p>10 Q. And were you afraid of what they might</p> <p>11 do to you if you -- somebody might do to you if you</p> <p>12 did an Internet search on an FDA web site? Is that</p> <p>13 what you're telling me?</p> <p>14 A. I made an extremely conservative</p> <p>15 assumption that I was going to maintain electrical</p> <p>16 silence on this case for the most part.</p> <p>17 I think the only thing I did was pull</p> <p>18 up -- here I need to qualify this, I do remember</p> <p>19 pulling up Digoxin label. But I did not search</p> <p>20 Digitek.</p> <p>21 Q. Did the plaintiffs' lawyers instruct you</p> <p>22 not to go on the FDA web site to find relevant</p> <p>23 information about Digitek?</p> <p>24 A. No. I talked to them --</p> <p>25 MR. THOMPSON: Object to the form.</p>	<p>1 injured people; correct?</p> <p>2 A. Yes.</p> <p>3 Q. Okay. And so one key question would be</p> <p>4 did anyone ingest defectively manufactured Digitek,</p> <p>5 that would be important in the litigation; correct?</p> <p>6 A. Yes.</p> <p>7 Q. Okay. And if they did, how much and</p> <p>8 over what period of time, that would be another</p> <p>9 relevant question; right?</p> <p>10 A. Yes.</p> <p>11 Q. Okay.</p> <p>12 A. Wait. No, I hope I gave you the right</p> <p>13 information about my electrical silence.</p> <p>14 Q. Now --</p> <p>15 A. I think it's irrelevant, but okay.</p> <p>16 Q. Now, the --</p> <p>17 MR. THOMPSON: It's the most -- that's</p> <p>18 the most eloquent opinion of big pharma that I've ever</p> <p>19 heard.</p> <p>20 THE WITNESS: It's of Google, actually.</p> <p>21 BY MR. DEAN:</p> <p>22 Q. Now, you've had a chance to review</p> <p>23 Exhibit 38 last night, I believe; correct?</p> <p>24 A. Mr. Thompson read sections of it to me.</p> <p>25 Q. Oh, you have -- so you have just -- you</p>
Page 127	Page 129
<p>1 THE WITNESS: I talked to them about the</p> <p>2 electrical silence. I asked them not to send me</p> <p>3 documents by e-mail. And I believe I told them</p> <p>4 exactly what I was telling you.</p> <p>5 And maybe it is completely irrelevant,</p> <p>6 but I had no idea of the impact. And I have to say,</p> <p>7 I'll modify it, I do remember going on for one drug</p> <p>8 label. But I -- no, I made a deliberate decision not</p> <p>9 to do independent research.</p> <p>10 BY MR. DEAN:</p> <p>11 Q. You --</p> <p>12 A. Even though I knew these documents</p> <p>13 existed. And if I need to act otherwise in the</p> <p>14 future, I will. But they were aware of this.</p> <p>15 Q. So to retrace my steps before we get</p> <p>16 back to this document, you are aware that the</p> <p>17 litigation that we're talking about are people who are</p> <p>18 alleging injuries from defective Digitek; correct?</p> <p>19 A. I know this is a liability case, that</p> <p>20 they consolidate all of the state-level cases into one</p> <p>21 federal case. They will be taking deposition on a --</p> <p>22 of a panel that will include a couple of federal</p> <p>23 judges.</p> <p>24 Q. But you're aware that the basic</p> <p>25 allegation is that there was defective Digitek that</p>	<p>1 haven't read the whole document then?</p> <p>2 A. No. I was told that I would probably be</p> <p>3 presented with this today.</p> <p>4 Q. What sections did Mr. Thompson read to</p> <p>5 you?</p> <p>6 You don't have to read the words. Just</p> <p>7 tell me the section.</p> <p>8 A. I can't find them.</p> <p>9 Q. Let me direct your attention and see if</p> <p>10 I can guess correctly.</p> <p>11 On Page 2, that paragraph, was that --</p> <p>12 the paragraph that starts Since the detection of the</p> <p>13 manufacturing problem, did he read that paragraph to</p> <p>14 you?</p> <p>15 A. That may have been one of them. The --</p> <p>16 the thing that I remember most clearly about that is a</p> <p>17 discussion -- we started to talk about my knowledge of</p> <p>18 the bioequivalence of generics. And, yes, I -- I see</p> <p>19 that.</p> <p>20 I can't remember that specifically</p> <p>21 because I halted and I started to entrain my own</p> <p>22 thoughts when they started talking about the</p> <p>23 bioequivalence and the reliability of generic drugs.</p> <p>24 Because I know about all the</p> <p>25 requirements for bioequivalence and the requirements</p>

33 (Pages 126 to 129)

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1 for 505(b).

2 But I'm also aware of cases where
3 generic manufacturing has been of variable quality and
4 it has impacted clinical outcomes.

5 Q. Let me stop you. I want you to, if you
6 can, answer my question.

7 And that is, what -- what parts of
8 Exhibit 38 did Mr. Thompson call to your attention
9 last night?

10 Did you see it last night or did he just
11 read parts of it to you?

12 A. He read it. And when he read me, I was
13 actually worrying about certain things I was going to
14 say today. So if he said something and it would
15 trigger thoughts and I had lapses of attention while
16 he was reading.

17 Q. Well, sometimes that happens to
18 Mr. Thompson.

19 A. No. It happens to me a lot because if
20 you say something to me and it kicks off a trigger
21 thought, I will follow it and then I'll come back, and
22 that's why I have you clarify things.

23 Q. Seriously, you said he made reference to
24 a couple points.

25 Have you ever read this document before

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1 now?

2 A. No.

3 Q. Before right now?

4 A. No.

5 Q. So this, as you're sitting here right
6 now, is the first time you've actually seen Exhibit
7 38; is that correct?

8 A. Yes.

9 Q. Okay. Now, I want to direct your
10 attention to Page 2 of that document. And the
11 paragraph that's about a third of the way down, which
12 I directed to you before, where it says Since the
13 detection of the manufacturing problem.

14 A. Since the detection --

15 Q. Do you see that paragraph?

16 A. Yes.

17 Q. Okay. Now, let me ask you some
18 questions about that.

19 Well, the first sentence says, Since the
20 detection of the manufacturing problems, FDA has been
21 actively engaged with this company to ensure that all
22 potentially affected lots of Digitek tablets have been
23 recalled.

24 You have no reason to doubt the accuracy
25 of the FDA's statement there, do you?

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1 A. I would think they would be extremely
2 cautious in their public statements given the fact
3 that, my understanding, there was a Congressional
4 inquiry on this. I think that these statements have
5 probably been very carefully worded.

6 Q. So you have no basis -- my question is,
7 you have no basis to disagree with that sentence, do
8 you?

9 A. No.

10 Q. Then the next sentence says, In our best
11 judgment, given the very small number of defective
12 tablets that may have reached the market and the lack
13 of reported adverse events before the recall, harm to
14 patients was very unlikely.

15 Did I read that correctly?

16 A. Yes.

17 Q. Do you have any basis to disagree with
18 the FDA's public statement in that sentence?

19 A. No. I do recall this being read. At
20 the time we were trying to access the other documents
21 on his computer. That's what distracted me.

22 I'm trying to remember how this occurred
23 because we were trying to bring in other documents all
24 at one time. And I made the statement that, yes, they
25 said harm to patients would be very unlikely.

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1 And that's where I brought up that you
2 would assume that they would have examined all
3 available data at the time they made that statement.

4 Because to have made that statement
5 without examining all available data would have left
6 them open to criticism had they been called before
7 Congress.

8 Q. So you assume that they did examine that
9 data; correct?

10 A. Yes. But I have -- I have no way to
11 substantiate that.

12 Q. But it is your assumption; correct?

13 A. Yes.

14 Q. Because you worked with the FDA and you
15 know how cautious they are about making public
16 statements, don't you?

17 MR. THOMPSON: Object to the form.

18 BY MR. DEAN:

19 Q. Go ahead.

20 A. I have no direct experience with this
21 type of procedure in the FDA.

22 I'm extrapolating from my experience as
23 an FDA reviewer when we would issue clinical hold
24 letters, and what they required of me in reviewing
25 data before I brought forward issues and they would

34 (Pages 130 to 133)

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Videotaped

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<p>1 issue a clinical hold letter.</p> <p>2 So I'm extrapolating from my experience</p> <p>3 and I'm making assumptions that they would be engaging</p> <p>4 caution because of the events of the last half a</p> <p>5 decade where they've come under increasing scrutiny.</p> <p>6 Q. And one of the things it's clear that</p> <p>7 they looked at before they made this statement was the</p> <p>8 reported Adverse Event Reports before the recall;</p> <p>9 correct?</p> <p>10 A. That's the data that I'm assuming they</p> <p>11 data mined from the AERS database.</p> <p>12 Q. So they had access to information that</p> <p>13 you've already told us you did not have access to;</p> <p>14 correct?</p> <p>15 A. Yes.</p> <p>16 Q. Okay. So this document, you would</p> <p>17 agree, was posted on July 9th of 2009 on their web</p> <p>18 site?</p> <p>19 A. Where's the post date?</p> <p>20 MR. THOMPSON: I object to the form of</p> <p>21 that question. I'm not sure how we know that.</p> <p>22 THE WITNESS: I can't find the posting</p> <p>23 date.</p> <p>24 BY MR. DEAN:</p> <p>25 Q. Do you know -- do have any knowledge as</p>	<p>1 the signal would have been valuable. I think there is</p> <p>2 a question of the scope of my work versus the scope of</p> <p>3 the cardiologist's work.</p> <p>4 My fixation on the signal has to do with</p> <p>5 the assessment of the actual risk or any potential</p> <p>6 risk during this period. But I didn't do the medical</p> <p>7 evaluation or signal detection.</p> <p>8 I'm formulating this because in</p> <p>9 addressing the issues I was asked to address, I would</p> <p>10 like to know -- I still think like a medical officer</p> <p>11 at the FDA. So these became disconcerting issues to</p> <p>12 me.</p> <p>13 And the fact that I was not given</p> <p>14 documents that someone else may have and I didn't have</p> <p>15 a fuller picture, and also the fact that the</p> <p>16 definitive evidence of the recalled drug was</p> <p>17 incinerated, so there's really no way to ever really</p> <p>18 know how much of those lots was affected, it left a</p> <p>19 big void.</p> <p>20 So that it became theoretical detection</p> <p>21 of risk. Did they look? Did they have procedures in</p> <p>22 place and in use? Were they documented? Were they</p> <p>23 affected by coding issues?</p> <p>24 Because I had no idea what was actually</p> <p>25 out there to be detected or the things that had been</p>
Page 135	Page 137
<p>1 to when this was posted?</p> <p>2 A. Not unless it is on this -- I can't -- I</p> <p>3 can't see the official date on this posting --</p> <p>4 Q. Okay.</p> <p>5 A. -- like you would have on a press</p> <p>6 release. No, I can't find it. It might be in my</p> <p>7 notes.</p> <p>8 Q. Do you know whether it's still on their</p> <p>9 web site?</p> <p>10 A. Well, the date it was printed was June</p> <p>11 15th of 2010.</p> <p>12 Q. So you assume it's still there;</p> <p>13 correct? Yes?</p> <p>14 A. Yes. Uh-huh.</p> <p>15 Are you waiting for my response?</p> <p>16 Q. No. I'm waiting for me -- myself. I'm</p> <p>17 waiting to formulate a question. So don't feel</p> <p>18 compelled to answer any more on my last one.</p> <p>19 Would you agree this information about</p> <p>20 the FDA looking at Adverse Event Reports on Digitek</p> <p>21 before the recall would have been relevant information</p> <p>22 to you in reaching issues of signal -- in commenting</p> <p>23 upon issues of signal detection?</p> <p>24 MR. THOMPSON: Object to the form.</p> <p>25 THE WITNESS: Yes. Any information on</p>	<p>1 written and been provided to Dr. Leikin or to the</p> <p>2 other expert witnesses.</p> <p>3 BY MR. DEAN:</p> <p>4 Q. Let's go back.</p> <p>5 You would agree that in the statement</p> <p>6 that we just read, it's clear that the FDA looked at</p> <p>7 adverse event information with regard to Digitek;</p> <p>8 correct?</p> <p>9 A. The assumption is that there was a data</p> <p>10 analysis behind that statement.</p> <p>11 Q. Which would have permitted the FDA, at</p> <p>12 least -- they relied, at least in part, on that</p> <p>13 assessment in reaching their conclusion; correct?</p> <p>14 A. Yes.</p> <p>15 MR. THOMPSON: I object to the form of</p> <p>16 that question.</p> <p>17 BY MR. DEAN:</p> <p>18 Q. Now, this sentence contained within this</p> <p>19 document would have provided relevant information to</p> <p>20 you in regard to formulating your pharmacovigilance</p> <p>21 opinions, wouldn't it?</p> <p>22 A. Yes. And --</p> <p>23 Q. And the plaintiffs' lawyers did not</p> <p>24 provide you with a relevant statement from the FDA</p> <p>25 that is directly relevant to the pharmacovigilance</p>

35 (Pages 134 to 137)

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Videotaped

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<p style="text-align: right;">Page 138</p> <p>1 charge that you were given to answer, did they?</p> <p>2 MR. THOMPSON: Object to the form.</p> <p>3 THE WITNESS: I was not provided any of</p> <p>4 the documentation that you are referring to.</p> <p>5 BY MR. DEAN:</p> <p>6 Q. And you were not provided with Exhibit</p> <p>7 38, were you?</p> <p>8 A. No. And I did not independently look</p> <p>9 for it, and I hope that I was not lapse -- lax in</p> <p>10 trying to seek it independently.</p> <p>11 Q. Is this the kind of information in</p> <p>12 Exhibit 38 that you referred to before as white space?</p> <p>13 A. It's a little bit out of the white</p> <p>14 space, but it is white space for me now that you</p> <p>15 brought it in. The truth of the matter is, the fact</p> <p>16 that I did not put this in context by going out and</p> <p>17 looking, I allowed that white space to occur.</p> <p>18 And I did it after discussing -- I</p> <p>19 believe that I discussed this Google issue over lunch</p> <p>20 with them.</p> <p>21 I don't know whether it was seen as</p> <p>22 important, but we sort of agreed that the best way to</p> <p>23 transfer information was either in paper or</p> <p>24 electronically.</p> <p>25 And they never asked me to go out and</p>	<p style="text-align: right;">Page 140</p> <p>1 those two stray cases on the total signal detection.</p> <p>2 The FDA says the lack of reported</p> <p>3 events. These older drugs that have had long market</p> <p>4 exposure and very little novel adverse events often</p> <p>5 have underreporting.</p> <p>6 And when you do the signal detection,</p> <p>7 you actually do it on the generic version, even when</p> <p>8 you're doing it on the branded compound, because</p> <p>9 people just report the drug.</p> <p>10 Q. If you -- let me interrupt you.</p> <p>11 If you were doing signal detection for a</p> <p>12 manufacturing defect, you'd only do it on the product</p> <p>13 that was manufactured by a given manufacturer;</p> <p>14 correct?</p> <p>15 A. But the reports are often silent from</p> <p>16 that and that has to be taken into account very</p> <p>17 carefully, because you don't want to do an inadequate</p> <p>18 document to be presented in this type of scenario.</p> <p>19 Q. Would you agree if you're trying to do</p> <p>20 signal detection to spot a manufacturing defect, you</p> <p>21 would look to the product manufactured by that</p> <p>22 particular manufacturer?</p> <p>23 A. When you have the information. But if</p> <p>24 the reports were silent, the default is to include</p> <p>25 them rather than to omit them.</p>
<p style="text-align: right;">Page 139</p> <p>1 look for additional information. They provided it to</p> <p>2 me. So I'm giving you the best of my recollection how</p> <p>3 this occurred.</p> <p>4 Q. The FDA did not say in here that the</p> <p>5 adverse event reporting procedures of Actavis were</p> <p>6 inadequate for them to form an opinion about the</p> <p>7 likelihood of injury to consumers, did they?</p> <p>8 MR. THOMPSON: Object to the form of</p> <p>9 that question. I believe it misstates the document.</p> <p>10 BY MR. DEAN:</p> <p>11 Q. Go ahead.</p> <p>12 A. They report on the lack of reported</p> <p>13 adverse events before the recall. That is probably</p> <p>14 valid.</p> <p>15 One of the things that I have discussed</p> <p>16 is that these systemic issues are samplings across</p> <p>17 multiple drugs, of which one or two out of any</p> <p>18 samplings are Digitek.</p> <p>19 They do contain cases that could be</p> <p>20 digitoxicity, they could be lack of efficacy. I don't</p> <p>21 know whether it was digitalis toxicity at normal</p> <p>22 digitalis levels, supratherapeutic digitalis levels,</p> <p>23 or in the face of renal failure.</p> <p>24 So I can't say anything about the cases</p> <p>25 I know and I can't say anything about the impact of</p>	<p style="text-align: right;">Page 141</p> <p>1 Q. There's no question pending.</p> <p>2 A. There was another point I wanted to</p> <p>3 make.</p> <p>4 Q. Why don't you let me formulate another</p> <p>5 question.</p> <p>6 A. Okay.</p> <p>7 Q. Does Exhibit 38 help you fill the void</p> <p>8 of missing information in this case?</p> <p>9 A. Yes. There's -- assuming that the FDA</p> <p>10 had rigorous review processes before making the</p> <p>11 statement, in light of the fact that this could end up</p> <p>12 in a court of law or in a testimony before Congress,</p> <p>13 this is an important piece of information.</p> <p>14 The lack of reported events is impacted</p> <p>15 by the low reporting rate of generic drugs until it's</p> <p>16 stimulated by an event such as a recall.</p> <p>17 Q. Doesn't this suggest to you, though,</p> <p>18 strongly suggest to you, that the FDA was satisfied</p> <p>19 with the adverse event reporting procedures in regard</p> <p>20 to Digitek before the recall?</p> <p>21 MR. THOMPSON: Object to the form.</p> <p>22 THE WITNESS: I'm going to be very</p> <p>23 careful with what I say. Because I don't know if</p> <p>24 they're required to be silent on certain things.</p> <p>25 In other words, they probably did not</p>

36 (Pages 138 to 141)

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<p>1 make an explicit statement of the impact. I'm sure</p> <p>2 they were very careful about the wording.</p> <p>3 But I have no information that would</p> <p>4 tell me -- I may need to talk to Mr. Thompson before I</p> <p>5 completely elucidate this, because I told him -- he</p> <p>6 asked me not to digress into this area, that it was</p> <p>7 outside of my scope.</p> <p>8 And either I should be silent or I</p> <p>9 should speak to him before I completely comment on --</p> <p>10 on this.</p> <p>11 BY MR. DEAN:</p> <p>12 Q. Well, that's not --</p> <p>13 A. It's not permissible?</p> <p>14 Q. With the background you've given us, I</p> <p>15 don't think that's an appropriate conversation for --</p> <p>16 to be had at this point. I think you need to answer</p> <p>17 my question.</p> <p>18 A. Okay. I have not been provided any</p> <p>19 information that says that there was an investigation</p> <p>20 after the consent decree where anyone went in and data</p> <p>21 mined the Actavis database.</p> <p>22 There's two ways to look at it, what</p> <p>23 events are coded.</p> <p>24 Because at the time of the 2008</p> <p>25 inspection, there's still investigator observations of</p>	<p>1 MR. DEAN: Excuse me. Could -- could</p> <p>2 you just read back my question and the answer.</p> <p>3 (The court reporter read back the</p> <p>4 following:</p> <p>5 "QUESTION: Do you think the FDA would</p> <p>6 have issued this statement unless they were satisfied</p> <p>7 with the reporting procedures of Actavis in regard to</p> <p>8 Digitek? Yes or no?"</p> <p>9 "ANSWER: I think the answer is yes,</p> <p>10 but --")</p> <p>11 THE WITNESS: I believe that the FDA was</p> <p>12 very, very careful to take into account the impact of</p> <p>13 compliance with reporting procedures by Actavis at the</p> <p>14 time they issued that statement.</p> <p>15 BY MR. DEAN:</p> <p>16 Q. And would you agree that if they had</p> <p>17 been satisfied with those procedures, they would not</p> <p>18 have issued the statement?</p> <p>19 A. I'm going to say yes, but I really don't</p> <p>20 know.</p> <p>21 Q. Okay. Thank you.</p> <p>22 Now, you -- a few minutes ago, you</p> <p>23 talked -- you talked -- you mentioned some product</p> <p>24 that was incinerated. What did you have reference to?</p> <p>25 MR. THOMPSON: Mr. Dean, are you -- are</p>
Page 143	Page 145
<p>1 unreported serious cases and there's a statement made</p> <p>2 by one of the employees about submitting cases from</p> <p>3 2006.</p> <p>4 Now, the remediation is outlined in the</p> <p>5 correspondence, including the PSURs for aggregate</p> <p>6 reporting. And the comment by the company employee</p> <p>7 talked about how far back they would go.</p> <p>8 In other words, they didn't want to go</p> <p>9 back before the acquisition. And I have no way to</p> <p>10 completely put that in context.</p> <p>11 So there's no data mining -- there's two</p> <p>12 ways to data mine. One is the coded cases and the</p> <p>13 other is to say the coding is defective, we're going</p> <p>14 to text search the narratives.</p> <p>15 And what if the narratives are only 50</p> <p>16 percent coded? There could be undetected signal.</p> <p>17 And in this case, it's unlike some of</p> <p>18 the other cases I've heard of where they have done</p> <p>19 those investigations. So I don't know how to comment</p> <p>20 to you.</p> <p>21 Q. Do you think the FDA would have issued</p> <p>22 this statement unless they were satisfied with the</p> <p>23 reporting procedures of Actavis in regard to Digitek?</p> <p>24 Yes or no?</p> <p>25 A. I think the answer is yes, but --</p>	<p>1 we through with Exhibit 38?</p> <p>2 MR. DEAN: I think we are, Mr. Thompson.</p> <p>3 MR. THOMPSON: So you're not going to</p> <p>4 question her on the other four bullet points under</p> <p>5 that paragraph; is that right?</p> <p>6 MR. KAPLAN: Well, I'm going to object</p> <p>7 to counsel making statements or inquiries here.</p> <p>8 That's entirely inappropriate.</p> <p>9 I move that that be stricken.</p> <p>10 MR. THOMPSON: All right. Well, let me</p> <p>11 then make --</p> <p>12 MR. KAPLAN: This is an examination by</p> <p>13 Mr. Dean. He can ask whatever questions he wants and</p> <p>14 it's just inappropriate for you to comment.</p> <p>15 If you do any more commenting, we're</p> <p>16 going to be talking to Judge Goodwin about that.</p> <p>17 MR. THOMPSON: All right.</p> <p>18 Let's talk to Judge Goodwin about the</p> <p>19 presentation of Defendant's Exhibit to my expert and</p> <p>20 intimating that this was withheld from her, when, in</p> <p>21 fact, this is a document that was withheld from us</p> <p>22 until last week when it was delivered to us from</p> <p>23 Mr. Anderton, who indicated that he had given it to</p> <p>24 his expert, but it had not been produced to us.</p> <p>25 MR. DEAN: This is not a company</p>

37 (Pages 142 to 145)

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1 document. We're not -- we can have this discussion --
 2 MR. THOMPSON: Well, your testimony --
 3 your testimony to her has begun to intimate that the
 4 plaintiffs' counsel has done this and done that.
 5 And, in fact, I'm looking at a document
 6 that you've confronted her with which was never
 7 produced to us in regular time and which was never
 8 available to be sent to her.
 9 MR. DEAN: Never available to be sent to
 10 her because it was on the FDA web site?
 11 BY MR. DEAN:
 12 Q. Let's go back to the question that I
 13 just asked you about. You, a few minutes ago, used
 14 the word "incinerated," I think; is that correct?
 15 A. I will tell you the information, and I
 16 don't -- it's probably in here. It may not be. But
 17 in the recall packet, they have forms to fill out to
 18 send the recalled product to Minnesota for
 19 destruction. We can pull that out.
 20 My impression, and I am willing to be
 21 corrected if I am wrong, is that there was no
 22 analytical work done on that recalled product before
 23 it was incinerated.
 24 Q. So you're talking about -- when you say
 25 "recalled product," you're speaking about the recalled

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1 Digitek in 2008; correct?
 2 A. I think it went from June 6, 2006
 3 through 2008.
 4 Q. Right.
 5 It was announced in 2008, but going back
 6 for a couple years. So that -- that's fair. So that
 7 was the time of the -- the product that first went on
 8 the market in 2006, some of that was recalled.
 9 But your testimony is that when that
 10 product got recalled, you believe that product was
 11 incinerated; correct?
 12 A. This is why I did this document. I
 13 wanted to be very, very careful. I have a fixed idea
 14 in my mind from reviewing the documents that this
 15 occurred. If I am wrong, I will stand corrected.
 16 Q. Well, what is your understanding as to
 17 how much of the product was incinerated?
 18 A. I don't know. I was -- it may be a
 19 white space where I was not provided any information
 20 on what was done with that product.
 21 But the recall package indicated it
 22 would be shipped for destruction, and I was not
 23 provided any evidence to say that it was analyzed
 24 before it was destroyed.
 25 Q. Okay. Let's go on.

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1 Do you have Exhibit 261 in front of you,
 2 Dr. Frank?
 3 A. Yes.
 4 Q. Good. Let's see if I do.
 5 All right. I'm on Page 4, which is the
 6 first page of -- are you with me there? And it's in
 7 the section on Background.
 8 A. Yes.
 9 Q. I want to direct your attention to the
 10 second paragraph.
 11 A. Uh-huh.
 12 Q. You reference PSUR preparation; right?
 13 A. Yes.
 14 Q. Here's my question to you, a very simple
 15 question: Does a generic manufacturer who distributes
 16 product only in the United States have any duty to
 17 submit PSURs?
 18 A. Their legal obligation is U.S. Periodic
 19 Reports. But the FDA accepts PSURs in lieu of the
 20 U.S. Periodic Reports for the aggregate reporting.
 21 So many companies that operate globally
 22 produce one PSUR and then it is modified with
 23 appendices for country-specific reporting
 24 requirements.
 25 Q. Would you agree that if a -- any drug

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1 manufacturer, brand name or generic, only distributes
 2 product in the United States, they do not have to
 3 submit a PSUR, do they?
 4 A. No. If it's just U.S., it can be just a
 5 U.S. Periodic Report.
 6 Q. Thank you.
 7 Now, in the third paragraph, you've got
 8 some information regarding the company history, do you
 9 not?
 10 A. Yes.
 11 Q. Where did that come from?
 12 A. It was abstracted from the Establishment
 13 Inspection Reports and from the company correspondence
 14 to the FDA, which is where I found the dates, the
 15 consent decrees, the day it was -- the defect was
 16 lifted in 2001, the dates of the acquisition.
 17 All of this was taken and it should go
 18 back to Reference 14, Page 7.
 19 Q. Okay.
 20 A. I tried to annotate every statement in
 21 here. If there's an error in my annotation, I will go
 22 back and do the due diligence, because these should
 23 all be annotated from the documents I was provided.
 24 The way this --
 25 Q. No. Let me -- just wait for another

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<p>1 question, please.</p> <p>2 In the fifth paragraph, the one that</p> <p>3 starts, There is little or no information, I take it</p> <p>4 that you were provided no information about either</p> <p>5 Amide or Actavis -- well, actually, you had the</p> <p>6 information about the 2004 incident; right?</p> <p>7 A. Yes.</p> <p>8 Q. So --</p> <p>9 A. That was provided -- yeah, that was --</p> <p>10 I'm not sure when it was -- when I wrote that, but,</p> <p>11 yes, there was -- the information became more</p> <p>12 intensive starting with this February 2006 inspection.</p> <p>13 Q. So is it fair to say you have no</p> <p>14 information before February 2006 about what might be</p> <p>15 termed alleged deficiencies in adverse event</p> <p>16 reporting? Is that fair?</p> <p>17 A. If you look at the timeline, the first</p> <p>18 inspection I was able to identify where I don't have</p> <p>19 the 483s or the reports was in Elizabeth, New Jersey,</p> <p>20 August 11th, '03 to August 14th, '03.</p> <p>21 It was specifically a post-marketing</p> <p>22 adverse drug experience inspection, and it was</p> <p>23 classified as NAI.</p> <p>24 Q. And what does that mean?</p> <p>25 A. No action indicated.</p>	<p>1 would -- if I needed, I would ask for more information</p> <p>2 to cover that period.</p> <p>3 Q. And where did you get the information</p> <p>4 that such an inspection took place?</p> <p>5 A. I can find it for you. Because this was</p> <p>6 a later edition, and I believe, and I might have to go</p> <p>7 back and verify, that it came out of this, the</p> <p>8 introduction of this Establishment Inspection Report.</p> <p>9 Q. That's Plaintiff's Exhibit 91, for the</p> <p>10 record.</p> <p>11 A. I had to go through the eyes of the FDA</p> <p>12 inspectors to find things that I was not provided.</p> <p>13 And there were some very good historical summaries.</p> <p>14 Q. Here's my question for you.</p> <p>15 If you can find it quickly, that's fine,</p> <p>16 but that's a long document. I'm ready to go on to</p> <p>17 another question if you can't find it.</p> <p>18 A. Okay.</p> <p>19 Q. Are you ready to go on?</p> <p>20 A. Yes.</p> <p>21 Q. Here's my simple question to you: On</p> <p>22 this, what you've labeled Inspection 1, Elizabeth, New</p> <p>23 Jersey, in 2003, do you know whether that referred --</p> <p>24 that that was a inspection relating to Digitek or to</p> <p>25 totally different product lines?</p>
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<p>1 Q. And do you believe that what you've</p> <p>2 marked as Exhibit -- I'm sorry -- it's what is</p> <p>3 referenced as Inspection 1 related to a company called</p> <p>4 Amide or related to another company -- or related to a</p> <p>5 company that was operating in Elizabeth, New Jersey?</p> <p>6 A. No. It came from one of these documents</p> <p>7 that was either an FDA inspection of Amide or one of</p> <p>8 the correspondences between Amide activists and the</p> <p>9 FDA.</p> <p>10 And so this was within one of the</p> <p>11 acquired companies, and it was the site. I was -- I</p> <p>12 was more interested in sites and how pharmacovigilance</p> <p>13 was moved.</p> <p>14 There were two things I was trying to</p> <p>15 answer: What sites were inspected, what sites were</p> <p>16 inspected for pharmacovigilance and how</p> <p>17 pharmacovigilance was moved multiple times?</p> <p>18 And was there anything remaining after</p> <p>19 the consent decree was lifted? Was this pristine at</p> <p>20 the time the consent decree was lifted and then there</p> <p>21 was a decline in function, or was there a -- were</p> <p>22 there persistent issues?</p> <p>23 And this was important because it was an</p> <p>24 NAI inspection in 2003, and it was a very small window</p> <p>25 of insight, and so I documented it there. And then I</p>	<p>1 Do you know?</p> <p>2 A. No.</p> <p>3 Q. Okay.</p> <p>4 A. Any --</p> <p>5 Q. Okay. You don't; right?</p> <p>6 A. No.</p> <p>7 Q. Let's just leave it at that, I'll go on</p> <p>8 and ask you another question.</p> <p>9 A. I apologize for my lack of annotation on</p> <p>10 this.</p> <p>11 Q. But whether it was Digitek or some other</p> <p>12 product that was being commented on, it was NAI which</p> <p>13 would not raise any alarm bells with you, would it?</p> <p>14 A. I put that in there as a pertinent</p> <p>15 negative.</p> <p>16 Q. Okay. Thank you.</p> <p>17 Now, then you talk about the double-</p> <p>18 thick Digitek in July 2004. We've already spoken</p> <p>19 about that, so I'm not going to question you any more</p> <p>20 about that sentence.</p> <p>21 Then you say, In 2005 there was an MHRA</p> <p>22 inspection that resulted in an inspection observation</p> <p>23 on October 25 of inadequate information on transfer of</p> <p>24 expedited cases.</p> <p>25 You were never able -- strike that.</p>

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1 Did you ask for the documentation, the
 2 backup on that? Did you ask for it?
 3 A. I talked to Pete Miller about this on
 4 June 2nd.
 5 Q. Did you ask him for it?
 6 A. Yes.
 7 Q. Did you get it?
 8 A. They were not aware of any MHRA
 9 inspection reports in the discovery. I think, if I'm
 10 not mistaken, there may have been others.
 11 The fact that there was an MHRA
 12 inspection in 2005 implies a repeat inspection in a
 13 two-year cycle. But that's an assumption.
 14 But, no, I have no information about
 15 MHRA inspection findings other than the fact that one
 16 of those was detected at the time of the due diligence
 17 in the acquisition, and the decision was made to
 18 implement the agreement between Amide and the MHRA
 19 after the merger in March.
 20 And there was FDA inspection findings of
 21 this noncompliance that sort of coincided with them.
 22 Q. Did you understand this to be a -- first
 23 of all, MHRA is a European regulatory agency; correct?
 24 A. Yes.
 25 Q. Did you understand this -- did you

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1 understand this reference to the MHRA inspection to
 2 deal with a reporting issue as a result of corporate
 3 acquisitions?
 4 A. No. But the MHRA --
 5 Q. You did not; is that right?
 6 A. No. This was -- this was before the
 7 acquisition.
 8 It was independent, and it was -- I
 9 believe it was a finding of the due diligence at the
 10 time of the acquisition, and it's the only information
 11 I have on the due diligence in pharmacovigilance.
 12 Q. So you don't know what the eventual
 13 outcome of that inspection was, do you?
 14 A. There was an agreement, and I know the
 15 date of the implementation and I know that it was
 16 communicated to the FDA because of concerns with
 17 transfer between Copenhagen and the U.S.
 18 Q. Do you know whether the FDA was
 19 satisfied with the conclusion on that?
 20 A. This I believe --
 21 Q. Either you know or you don't. Which is
 22 it?
 23 Do you know whether they were satisfied
 24 or don't you?
 25 A. May I give you an answer based on my

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1 best recollection?
 2 Q. First of all, do you know?
 3 A. I believe this came from the Amide
 4 response immediately following the 2006 inspection.
 5 And the FDA responses reiterated concern with serious
 6 underlying systemic issues.
 7 But I can't recall the FDA ever
 8 responding to this particular MHRA inspection.
 9 And I inquired whether Digitek was
 10 marketed outside of the U.S. and the potential impact
 11 of the MHRA inspection on collection of Digitek cases,
 12 per se.
 13 And, to my knowledge, and to the
 14 knowledge of all the counsel that I had, Digitek is
 15 only marketed in the U.S. And so the transfer of
 16 these cases from Copenhagen to the U.S. did not impact
 17 compliance with Digitek or signal detection.
 18 Q. Did you put that in your report?
 19 You didn't put that in your report, did
 20 you?
 21 A. No. It was verbal communication.
 22 Q. Wouldn't a fair and objective expert
 23 witness have noted in a Digitek case that an
 24 observation about an MHRA inspection didn't have
 25 anything to do with Digitek?

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1 MR. THOMPSON: Object to the form.
 2 THE WITNESS: Possibly. If I do it
 3 again, I'll be more careful with the annotation. I
 4 would say --
 5 BY MR. DEAN:
 6 Q. But you do agree that, as you understand
 7 the facts now, that Digitek would not have been
 8 impacted by that particular inspection; correct?
 9 A. No.
 10 Q. Is that correct?
 11 A. We clarified this, and at this point, my
 12 understanding is there are Digoxin cases, but they're
 13 not Digitek. That I could assume that all Digitek
 14 cases would arise from the U.S.
 15 I have nothing other than verbal
 16 confirmation. So I -- yeah, I'll have to say yes.
 17 Okay. This is -- I'm pulling in extraneous
 18 information trying to clarify.
 19 But it does have impact on the
 20 assessment of the systemic issues because they made
 21 arbitrary decisions based on this, the implementation
 22 of this MHRA agreement, that were upsetting to the FDA
 23 and did lead to a 483.
 24 Q. And do you know the final position of
 25 the FDA in response -- or in respect to their level of

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1 satisfaction with this MHRA inspection?

2 Are you aware of the final word on that
3 from the FDA?

4 A. The implementation of this agreement
5 with the MHRA was effective on March 1st. And for
6 reasons unknown to me, Copenhagen sent a batch of
7 cases two to three months later, and it's in one of
8 the response letters.

9 They made a decision and wrote a note to
10 the file to call their initial receipt date the day
11 they got these from Copenhagen, rather than the date
12 they were first received in Copenhagen.

13 And the FDA made an observation of that
14 and required the company to make a change, and there's
15 a note to the file of the change in that process.

16 But they made an -- they made a
17 decision, and I don't know who ratified it, who was
18 given the governance, but the ineffective
19 implementation or somehow the delay in this
20 implementation led to further FDA inspection findings.

21 Because the transfer did not occur
22 immediately at March 1st. The first transfer was a
23 batch a couple of months later and led to
24 noncompliance. That's sort of why I left it in.

25 Q. But my question to you is, do you know

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1 the final resolution of this in the eyes of the FDA?

2 A. It was inspection finding that required
3 remediation, and I do not recall any inspectors
4 assessing the adequacy of the corrective action.

5 Q. Let's turn to Page 5. The second
6 paragraph on Page 5 you recite the history of the
7 warning letters and the responses.

8 Well, there was a 483 and a response and
9 a warning letter and a response and you recite all
10 that history, do you not?

11 A. Second paragraph, Page 5?

12 Q. Page 5.

13 A. Yes.

14 Q. And did you -- you've talked before
15 about white spaces. Is there a white space in this
16 paragraph where there is, in all likelihood, a missing
17 document?

18 A. I documented the missing letters. But
19 it's not -- I don't know that I translated the
20 documented missing letters in here into the
21 conclusion.

22 This -- this paragraph, there were
23 issues with the accuracy of the responses from
24 February 28th and February 8th, and the FDA took
25 issues with those.

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1 But they -- the reason this is in there
2 is they warned the company that these specific
3 violations are serious and they may be symptomatic of
4 underlying problems.

5 And I was asked to assess systemic
6 issues. And I wasn't given any Digitek subsets, so I
7 started pulling in a lot of things, like MHRA
8 inspections. But the FDA gave them warning.

9 And I started looking for has anybody
10 given me evidence of the compliance remediation plan,
11 the tracking of it with Metrix, and its adequacy.

12 So this is put in here because the FDA
13 warned that they needed to assess broader systemic
14 issues.

15 Q. So at this point, as you read that set
16 of correspondence, as a pharmacovigilance expert, you
17 have a concern that they may not have engaged in the
18 right corrective procedures; correct?

19 A. Or else I was not given the documents.
20 Because they produced a QSIP, and it's huge, and they
21 said they'd send it to me, that I could look at it.

22 Q. Who said that?

23 A. Pete Miller did.

24 Q. But you -- did you request it?

25 A. Yes.

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1 Q. Did he send it to you?

2 A. No.

3 Q. Okay. Now, isn't it -- when you see a
4 history of 483s and warning letters like this, isn't
5 it usual for the FDA at the end of the day, at the end
6 of the sequence, to tell the company whether they've
7 satisfactorily engaged in corrective procedures or
8 whether they're still deficient?

9 Isn't that commonplace?

10 A. The FDA revised warning letter, I think
11 this was in July, reiterates the findings, talks about
12 the inadequacy of the response, and this is a quote.

13 Now, my question is, did the company
14 engage in any type of root cause analysis or process
15 evaluation to assess broader systemic issues, and did
16 they put in place a remediation program that was
17 adequately implemented and tracked.

18 The bottom line that I came to based on
19 what I could see is they had similar repeat inspection
20 findings in 2008, there was a statement that one of
21 the company -- and it was Mr. Delicato, about cases in
22 2005, which I thought were part of this remediation.

23 And I don't know all the circumstances
24 about this or the negotiations or what would be
25 submitted, but the white spaces, what they did, what

41 (Pages 158 to 161)

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<p>1 they did in the QSIP, but the outcome was the FDA said</p> <p>2 there's a total failure for quality systems.</p> <p>3 There's still repeat pharmacovigilance</p> <p>4 findings.</p> <p>5 And then when the recall occurred --</p> <p>6 Q. Who said there was a total failure of --</p> <p>7 a total failure of what?</p> <p>8 A. That's a quote, and that might be --</p> <p>9 Q. That's a quote from who?</p> <p>10 A. An FDA inspector in either the closeout</p> <p>11 meeting or in this EIR. And because this is a</p> <p>12 verbatim --</p> <p>13 Q. And, in fairness, that was a quote about</p> <p>14 total failure of quality control in regard to quality</p> <p>15 control, not in regard to pharmacovigilance. Do you</p> <p>16 agree?</p> <p>17 A. I was unable to sort out the quality</p> <p>18 unit. It -- for the most part, it was addressing</p> <p>19 manufacturing issues.</p> <p>20 But my question is, there's usually</p> <p>21 quality systems that control pharmacovigilance quality</p> <p>22 and product complaint and clinical research.</p> <p>23 There should have been some sort of a</p> <p>24 quality system for all of these business critical</p> <p>25 functions.</p>	<p>1 (Witness reviews document.) Okay.</p> <p>2 They --</p> <p>3 Q. You've never seen this document before,</p> <p>4 have you?</p> <p>5 A. No.</p> <p>6 Q. And we can agree that it is a letter</p> <p>7 from the FDA to Actavis Totowa dated January 3, 2007;</p> <p>8 correct?</p> <p>9 A. Yes. And I don't have this in the white</p> <p>10 space, so I have no indication this letter existed</p> <p>11 until you just gave this to me.</p> <p>12 Q. This is the first time you've ever seen</p> <p>13 it in your life and the first time you're even aware</p> <p>14 of its existence; correct?</p> <p>15 A. Yes.</p> <p>16 Q. And we would agree that it says, in the</p> <p>17 second paragraph, New Jersey District has reviewed</p> <p>18 your response regarding adverse drug experience</p> <p>19 reporting deficiencies. Your corrective action and</p> <p>20 the revised procedures appear to be satisfactory.</p> <p>21 That's what it says; correct?</p> <p>22 A. Absolutely.</p> <p>23 MR. THOMPSON: I object to taking that</p> <p>24 out of context.</p> <p>25 BY MR. DEAN:</p>
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<p>1 Q. Can we agree that if there is a letter</p> <p>2 from the FDA to Actavis saying that they were</p> <p>3 satisfied with the company response to the</p> <p>4 pharmacovigilance issues contained in the warning</p> <p>5 letter of August 15, 2006, you've never seen it, have</p> <p>6 you?</p> <p>7 A. No. I've not -- I did not see -- I did</p> <p>8 not identify in my review any interim FDA</p> <p>9 communication that said they were satisfied. If it's</p> <p>10 my error, I stand corrected. There are letters that I</p> <p>11 was not provided, and I documented that.</p> <p>12 Q. Did you -- how did you document what you</p> <p>13 were not provided? How would you know how to document</p> <p>14 it?</p> <p>15 A. Oh, boy. I laid out this timeline for</p> <p>16 myself. Inspections I found are in red. Any</p> <p>17 information I have on the inspections was there unless</p> <p>18 there was a full report.</p> <p>19 In blue were the company's responses.</p> <p>20 And the black are these intercurrent communications.</p> <p>21 And here in the timeline is part of my attempt to</p> <p>22 document things that were not included to me.</p> <p>23 Q. Let me hand you what we marked as</p> <p>24 Defendant's Exhibit 87.</p> <p>25 A. All right.</p>	<p>1 Q. So the -- in your paragraph on Page 5,</p> <p>2 you referenced the 483s and the warning letters on the</p> <p>3 pharmacovigilance issues, but you didn't reference</p> <p>4 Exhibit 87 because you were unaware of it; correct?</p> <p>5 A. Yes. I expressed concerns multiple</p> <p>6 times about missing information like this that could</p> <p>7 impact on my --</p> <p>8 Q. And it's clear that the FDA was</p> <p>9 satisfied with that response, wasn't it?</p> <p>10 MR. THOMPSON: Object to the form of the</p> <p>11 question.</p> <p>12 THE WITNESS: Well, the FDA is</p> <p>13 satisfied. I don't know -- August 15th. Revised</p> <p>14 warning letter.</p> <p>15 Wait a second.</p> <p>16 We acknowledge dated September 6th, the</p> <p>17 company responds, the procedures, I don't have October</p> <p>18 26th. There is a clear statement that corrective</p> <p>19 actions and the revised procedures were satisfactory.</p> <p>20 BY MR. DEAN:</p> <p>21 Q. And you don't have any basis to disagree</p> <p>22 with the FDA position on that, do you?</p> <p>23 A. The company --</p> <p>24 MR. THOMPSON: I object to the form of</p> <p>25 the question.</p>

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Videotaped

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<p>1 THE WITNESS: I do not believe I've seen 2 the additional revised procedures on October 25th, and 3 so I cannot make an independent determination. 4 And in order to really give you an 5 accurate opinion, I should probably read -- re-read 6 the September 6th. 7 However, I think that in a court of law, 8 this FDA opinion would supersede my opinion unless I 9 could really provide evidence to the contrary. 10 BY MR. DEAN: 11 Q. Thank you. 12 So as of January 3, 2007, we can agree 13 that the FDA was satisfied it had received all adverse 14 reaction reporting from Amide or for Actavis Totowa 15 that had been raised by the 483 and the warning 16 letter; correct? 17 MR. THOMPSON: I object to the form of 18 the question and I entreat Dr. French (sic) to please 19 read the entire document before she answers a single 20 out-of-context sentence. 21 MR. DEAN: It's Dr. Frank, I believe. 22 MR. THOMPSON: I -- then I've just -- 23 I'm probably in the wrong place at the wrong time. 24 THE WITNESS: This is very, very 25 difficult because these corrective actions have a</p>	<p>1 MR. DEAN: Do you want to keep going or 2 do you want to take a short break? 3 MR. THOMPSON: I think we ought to take 4 a break as we go, you know. 5 MR. DEAN: I think we've been going 6 about an hour. Let's take a short break. 7 I don't want to take a long one. 8 MR. THOMPSON: Sure. 9 MR. DEAN: Let's go off the record. 10 VIDEO OPERATOR: Going off the video 11 record. 12 The time is 2:06 p.m. 13 (A recess was taken from 2:06 p.m. to 14 2:16 p.m.) 15 VIDEO OPERATOR: We are now back on the 16 video record. 17 This is the start of Tape 4. 18 The time is 2:16 p.m. 19 BY MR. DEAN: 20 Q. Dr. Frank, in regard to Exhibit 87, 21 we've -- before we broke, you agreed that this 22 provided relevant information on the status of the 23 adverse event reporting at Actavis; correct? 24 MR. THOMPSON: Object to the form. 25 THE WITNESS: I think it's an important</p>
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<p>1 scope. And I'm reading this out of context in the 2 scope, so I can't track what the corrective actions 3 were or the procedures. 4 And I have no information about the 5 adequacy of the corrective actions during the future 6 inspection because there's both the plan and the 7 implementation of the plan. 8 So this is basically saying they did -- 9 they did a corrective action. And the District Office 10 found it satisfactory, and I'm assuming that they 11 could implement it without revision. 12 BY MR. DEAN: 13 Q. Earlier, much earlier this morning, you 14 told us that what you were relying on this -- in this 15 case was the FDA conclusions and not the underlying 16 documents. 17 Do you remember that? 18 A. Yes. There is -- I've not -- I don't 19 have a lot -- I just read 483s and established 20 inspection reports and letters. 21 Q. And so this is no different. This is an 22 FDA document with a final conclusion and you have no 23 basis to disagree with it; correct? 24 A. Not at present. 25 Q. Okay. Thank you.</p>	<p>1 piece of information that I would have liked to have 2 had when I -- when I came up with the conclusion. 3 I'd like to put it in context with the 4 decision to move pharmacovigilance from Totowa to 5 Elizabeth, because Elizabeth apparently was compliant. 6 Remember I told you about that NAI 7 inspection. It's a very, very important piece of 8 information that could -- it clearly has a material 9 impact on the analysis. I cannot immediately put it 10 in context with the overall picture. 11 I'm assuming that you're going to 12 continue to present me with further information that's 13 extremely important to the assessment. But I do not 14 deny that this is important. 15 BY MR. DEAN: 16 Q. Well, your first conclusion -- your 17 first basic conclusion, as I understand your summary 18 of your report, was that there were -- it's not clear 19 that there were appropriate pharmacovigilance 20 procedures in place at Actavis Totowa; is that your -- 21 a fair summary of one of your primary conclusions? 22 A. The original assessment in the response 23 letter talked about the inadequacies of the 24 interpretation of the regulations and an 25 implementation of the procedures.</p>

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<p>1 Q. Now, let me interrupt you. I'm not</p> <p>2 talking about what was in the letter. I'm talking</p> <p>3 about the summary you gave me this morning about the</p> <p>4 two key points you were --</p> <p>5 A. Yes.</p> <p>6 Q. -- trying to make in your report.</p> <p>7 And one, I think, was the adequacy of</p> <p>8 the pharmacovigilance procedures and its impact on</p> <p>9 signal detection and that you were asked to evaluate</p> <p>10 the system that was in place; correct?</p> <p>11 A. As much as possible, yes.</p> <p>12 Q. And would you agree that this document</p> <p>13 establishes, at least in the eyes of the FDA as of</p> <p>14 January of 2007, that appropriate procedures were in</p> <p>15 place?</p> <p>16 MR. THOMPSON: Object to form. I think</p> <p>17 it mischaracterizes the document.</p> <p>18 THE WITNESS: It establishes that</p> <p>19 appropriate corrective actions were presented to the</p> <p>20 agency and that the revised procedures were</p> <p>21 satisfactory.</p> <p>22 But it does not establish that there</p> <p>23 were satisfactory procedures in place during the total</p> <p>24 period affected.</p> <p>25 BY MR. DEAN:</p>	<p>1 interpretation of the regulations.</p> <p>2 And I believe the specifics were in</p> <p>3 actually assessing 15-day alerts.</p> <p>4 I think everything was stamped as a</p> <p>5 15-day alert and sent in without assessment of</p> <p>6 seriousness or expectedness. There were issues</p> <p>7 documented at the inspection and by the response</p> <p>8 letters that required the corrective actions.</p> <p>9 Q. Here's my question. It's a very simple</p> <p>10 question. Would you like to revise your opinion in</p> <p>11 light of Exhibit 87?</p> <p>12 A. I can't completely because they required</p> <p>13 corrective actions, which implies deficiencies, either</p> <p>14 in the procedures or in the compliance with the</p> <p>15 procedures.</p> <p>16 So there was an issue that required</p> <p>17 corrective action and required the revision of the</p> <p>18 procedure.</p> <p>19 It's the revised procedures that are</p> <p>20 satisfactory, not the ones that were revised. Not the</p> <p>21 baseline.</p> <p>22 So I have to be very, very careful and</p> <p>23 think -- I mean, for me to completely revoke</p> <p>24 everything looking at one letter and not sitting down</p> <p>25 and carefully analyzing it is a little dangerous.</p>
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<p>1 Q. Well, your opinion about inappropriate</p> <p>2 procedures was based upon -- primarily upon the series</p> <p>3 of 483s and warning letters in regard to</p> <p>4 pharmacovigilance, wasn't it?</p> <p>5 A. Yes. The assessment I made was only on</p> <p>6 what I was provided in the 483s and Establishment</p> <p>7 Inspection Reports and responses.</p> <p>8 Q. And so the primary -- that was the</p> <p>9 primary basis. And now you see Exhibit 87 for the</p> <p>10 first time which gives the FDA's final response to</p> <p>11 that series of observations and warning letters.</p> <p>12 And my question to you is --</p> <p>13 MR. THOMPSON: Object to the form.</p> <p>14 BY MR. DEAN:</p> <p>15 Q. -- would you like to revise your opinion</p> <p>16 stated in your report about the adequacy of the</p> <p>17 procedures at Actavis for pharmacovigilance reporting?</p> <p>18 A. I think that there were definite issues</p> <p>19 uncovered during the 2006 inspection. There was a</p> <p>20 shift from 2003, which was NAI, to 2006. And then</p> <p>21 there was a response letter talking about</p> <p>22 inappropriate interpretation.</p> <p>23 I think -- I think the important thing</p> <p>24 is to look at the actual wording. But the February</p> <p>25 8th, 2006 response talks about problems with</p>	<p>1 It's as dangerous as making an opinion</p> <p>2 on inadequate information.</p> <p>3 Because this -- the fact that there were</p> <p>4 corrective actions and procedures that were revised</p> <p>5 implies that there were problems that required the</p> <p>6 corrective actions in the revision. The FDA was okay</p> <p>7 with their plan.</p> <p>8 We do not know because we don't have the</p> <p>9 FDA confirmation of the adequacy of the corrective</p> <p>10 actions in a future inspection.</p> <p>11 If, indeed, this 2008 inspection that</p> <p>12 had me concerned correlates to this confirmation, then</p> <p>13 we have some observations consistent with inadequate</p> <p>14 implementation of this plan that they approved.</p> <p>15 So right now, this is very, very</p> <p>16 important.</p> <p>17 Q. This being 87?</p> <p>18 A. And potentially would modify it.</p> <p>19 Q. Number 87.</p> <p>20 A. But I still see that it's a -- it's a --</p> <p>21 still a complex and confusing chain of events where a</p> <p>22 company was on consent decree, they came off, they had</p> <p>23 apparently clean inspection in 2003, and then things</p> <p>24 started to happen that required corrective action.</p> <p>25 Do we know that it was corrected, or was</p>

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Karen A. Frank, M.D.

Videotaped

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<p>1 it corrected all by transferring to Elizabeth? I</p> <p>2 can't answer that at the moment.</p> <p>3 Q. Is it fair to say that Exhibit 87 raises</p> <p>4 significant questions in your mind as to the -- as to</p> <p>5 your opinion and that you would need more time to</p> <p>6 think about the issues and look at the underlying</p> <p>7 documents in order to stay and maintain with your</p> <p>8 opinion?</p> <p>9 MR. THOMPSON: Object to the form.</p> <p>10 THE WITNESS: I would like to be able to</p> <p>11 include all of this new, important evidence in a</p> <p>12 revised opinion and revise the white space. Because</p> <p>13 there could be more vulnerabilities.</p> <p>14 And I hope that's not too much of a</p> <p>15 hedge. But, yes, this should be incorporated into the</p> <p>16 -- into the opinion, but with very careful analysis.</p> <p>17 BY MR. DEAN:</p> <p>18 Q. Now, is it fair to say that as of</p> <p>19 January 3, 2007, the actual MedWatch reports that were</p> <p>20 mentioned in the 483 and the warning letter, isn't it</p> <p>21 clear that those had been submitted to the</p> <p>22 satisfaction of the FDA for this letter?</p> <p>23 A. This is where I got really --</p> <p>24 Q. Isn't that clear to you?</p> <p>25 A. It's not clear based on the totality of</p>	<p>1 submitted.</p> <p>2 I can't tell you based on what I've seen</p> <p>3 if this initial satisfactory answer does not have to</p> <p>4 be modified based on what happened in 2007 with the</p> <p>5 confirmatory inspection. I'm sorry.</p> <p>6 Q. You've told us before, if I'm correct,</p> <p>7 that it's -- you were uncomfortable in your role in</p> <p>8 this case because you didn't have full information and</p> <p>9 that it was -- I think your words were, it was</p> <p>10 dangerous to make an opinion based upon inadequate</p> <p>11 information. Do you agree with that?</p> <p>12 MR. THOMPSON: Object to the form.</p> <p>13 THE WITNESS: I think -- I actually</p> <p>14 think I said that. It may have been a mistake to say</p> <p>15 it. I think part of it is -- I do.</p> <p>16 BY MR. DEAN:</p> <p>17 Q. You agree that you said that; right?</p> <p>18 A. Yes.</p> <p>19 Q. And isn't that exactly where we're at</p> <p>20 here because you're saying that there -- that Exhibit</p> <p>21 87 raises significant questions, but you have</p> <p>22 inadequate information to totally evaluate the impact</p> <p>23 of Exhibit 87? Is that fair?</p> <p>24 A. Yeah, I think --</p> <p>25 Q. Is that fair?</p>
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<p>1 the evidence. And it might be -- I want to show you</p> <p>2 why, if I can find quickly. I can't search this</p> <p>3 electronically, but it's back in the 2008.</p> <p>4 I saw their agreement with the FDA for</p> <p>5 the remediation of the lack of compliance with the</p> <p>6 U.S. Periodic Reports. And that was approved, I</p> <p>7 think, actually by Washington. I should clarify that.</p> <p>8 But there's a statement back here, and I</p> <p>9 think it was the closeout, the minutes of the closeout</p> <p>10 meeting, where they're going back and talking about</p> <p>11 submitting reports from 2006.</p> <p>12 And I went -- that's when I really got</p> <p>13 worried and I do not yet have a clear picture of the</p> <p>14 events from 2006 to 2008.</p> <p>15 Why are they confronting them in 2006 --</p> <p>16 in 2008 about reports that were to have been submitted</p> <p>17 as part of the remediation in 2006, and the company is</p> <p>18 making a statement about not sure how far back they</p> <p>19 would go.</p> <p>20 I have no insight to that.</p> <p>21 I know that they initially did not want</p> <p>22 to remediate anywhere before they acquired, and I</p> <p>23 don't have a lot of insight into the regulatory risk</p> <p>24 decisions that were being made or why they're saying</p> <p>25 they have to discuss internally what will be</p>	<p>1 A. I think at that point I was provided</p> <p>2 information and I discussed this with counsel. What</p> <p>3 if they -- I have all of these questions, and I think</p> <p>4 there's information out there that they will present</p> <p>5 to me.</p> <p>6 What happens -- and I asked this at the</p> <p>7 June 2nd meeting of Megan Carter. What happens if I'm</p> <p>8 provided information that is material and requires me</p> <p>9 to modify my position?</p> <p>10 They said, we'll take it and revise the</p> <p>11 position, but we want a preliminary assessment.</p> <p>12 Q. Do you understand that these opinions</p> <p>13 have been filed with the court?</p> <p>14 A. Yes. I talked to them about this.</p> <p>15 Q. Were you concerned about that?</p> <p>16 A. Yes. I expressed that.</p> <p>17 Q. And was your concern that you didn't</p> <p>18 have enough information on which to base an informed</p> <p>19 opinion? Was that your concern?</p> <p>20 A. I was concerned that I had incomplete</p> <p>21 information where I would be vulnerable to being</p> <p>22 presented with further information that could lead me</p> <p>23 to modify my opinion.</p> <p>24 Q. And it turns out that that's happened</p> <p>25 and that you may well want to modify your opinion; is</p>

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<p style="text-align: right;">Page 178</p> <p>1 that correct?</p> <p>2 A. Possibly.</p> <p>3 Q. Okay.</p> <p>4 A. But the -- this does not yet explain</p> <p>5 away the 2008 observations and the statements that the</p> <p>6 company employee made about persistent nonreporting of</p> <p>7 cases in 2006.</p> <p>8 So while it's material, I don't think it</p> <p>9 can completely negate because --</p> <p>10 Q. Let's -- I'm sorry. You go ahead and</p> <p>11 finish. I want to talk about that in a minute, but I</p> <p>12 want you to finish.</p> <p>13 A. What is distilled down was 2006, the</p> <p>14 remediation program, and persistent observations in</p> <p>15 2008, and this unexplained comment about submission of</p> <p>16 cases that apparently were to have been submitted as</p> <p>17 part of the 2006 remediation.</p> <p>18 So that is still -- and here I'm coming</p> <p>19 back to this, I asked them -- I told them this</p> <p>20 specifically, I said, this would be the basis of my</p> <p>21 opinion. And yet, all of this has not been taken into</p> <p>22 account. Should I proceed with this?</p> <p>23 I asked them very seriously what</p> <p>24 constitutes adequate documentation for the opinion,</p> <p>25 how much they can provide for me, how can -- how much</p>	<p style="text-align: right;">Page 180</p> <p>1 this -- we have to take this and revise the opinion.</p> <p>2 If I was given advice, please forgive my</p> <p>3 naivete, but I really made an attempt to deliver a --</p> <p>4 an adequate expert witness opinion given the</p> <p>5 circumstances.</p> <p>6 BY MR. DEAN:</p> <p>7 Q. Dr. Frank, isn't it fair to say that you</p> <p>8 are no longer comfortable in much of the information</p> <p>9 in your report?</p> <p>10 MR. THOMPSON: Object to the form.</p> <p>11 THE WITNESS: I think it requires</p> <p>12 revision based on new evidence. Yes, I'm -- I -- I</p> <p>13 think there's some things, such as the point -- time</p> <p>14 point in 2006 and the time point in 2008, that says</p> <p>15 there were problems with that.</p> <p>16 But I still do not have any real insight</p> <p>17 into the QSIP, and I only have a few observations in</p> <p>18 2008.</p> <p>19 And, yes, I think there's a great deal</p> <p>20 -- I think the -- I think that the comments on</p> <p>21 individual observations probably refer well back to</p> <p>22 the individual observations.</p> <p>23 But the absolute conclusions probably</p> <p>24 need to be modified based on the evidence that you've</p> <p>25 provided me.</p>
<p style="text-align: right;">Page 179</p> <p>1 I can request on any further discovery?</p> <p>2 I asked for a lot of guidance, and I</p> <p>3 trust that they gave it to me appropriately, is in</p> <p>4 taking the information they gave to me, what</p> <p>5 constituted a legitimate opinion before this was</p> <p>6 filed.</p> <p>7 This was not done haphazardly. I</p> <p>8 actually tried my best to render an opinion based on</p> <p>9 what I was granted.</p> <p>10 Q. But, as we sit here today, you are --</p> <p>11 the fact of the matter is, you -- at the time you</p> <p>12 rendered it, you were concerned about inadequate</p> <p>13 information.</p> <p>14 And now, as we sit here today, you have</p> <p>15 an even greater concern about inadequate information</p> <p>16 being provided to you in order to formulate this</p> <p>17 report; isn't that true?</p> <p>18 MR. THOMPSON: Object to the form.</p> <p>19 THE WITNESS: You've provided me exactly</p> <p>20 what I anticipated might happen and what I raised to</p> <p>21 the people that hired me and asked me to do this</p> <p>22 analysis for them. This is not unexpected.</p> <p>23 And I asked them how I should handle it</p> <p>24 and the risk and how I should respond to it when it</p> <p>25 occurred. And they said, what you do is you take</p>	<p style="text-align: right;">Page 181</p> <p>1 BY MR. DEAN:</p> <p>2 Q. And while I recognize -- while</p> <p>3 recognizing that the preparation of a report is an</p> <p>4 ongoing process, did you -- were you informed that the</p> <p>5 report that was filed with the Court was supposed to</p> <p>6 be a final report?</p> <p>7 Were you ever told that?</p> <p>8 A. I was told the deadline and I was told</p> <p>9 it would be reviewed. And I asked what I would do in</p> <p>10 this scenario. And I did have some discussion of the</p> <p>11 risk of this occurring.</p> <p>12 I assumed -- I -- no, I completely</p> <p>13 anticipated you would do this.</p> <p>14 This is why I'm receptive to it, and I'm</p> <p>15 very, very careful to look at it analytically to -- to</p> <p>16 accept what has to be accepted, but not to be foolish</p> <p>17 and under a state of anxiety back down when I need to</p> <p>18 be careful and analytical.</p> <p>19 I can err in either direction in this</p> <p>20 setting and I want to be very, very cautious.</p> <p>21 Q. Let's go to Page -- go back to Page 5 --</p> <p>22 A. Okay.</p> <p>23 Q. -- in the one, two -- third paragraph.</p> <p>24 A. Yes.</p> <p>25 Q. I want to get on to this reference to</p>

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1 Mr. Delicato in 2008 that you've mentioned before and
2 try to get into the right set of documents and ask you
3 some questions on that topic. Okay?

4 A. That's fine.

5 Q. Now, I think it's in the second sentence
6 of that paragraph.

7 It says, In addition, there are
8 implications of the FDA observation that, quote,
9 Mr. Delicato stated that unreported cases from January
10 and February 2006 would be submitted to the FDA.

11 However, Mr. Delicato informed me that
12 they did not have a definitive answer to how far back
13 they would go in reviewing unreported cases. He said
14 they would include this information in their written
15 response to the New Jersey District.

16 What -- is that a -- so that's from
17 Reference 15; is that right?

18 A. And it's in quotations and it's very
19 carefully placed there.

20 Q. Hang on. Let me see what 15 is. Okay.

21 So 15 is a May 2000 -- May 21, 2008 FDA
22 inspection report; correct?

23 A. Yes.

24 Q. All right. So let's get that in front
25 of us.

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1 I am handing you, Dr. Frank, what's
2 been --

3 VIDEO OPERATOR: Your microphone.

4 MR. DEAN: Sorry. Thank you.

5 BY MR. DEAN:

6 Q. Dr. Frank, I'm handing you what has
7 previously been marked as Defendant's Exhibit 62.

8 And the first page of this is a letter
9 from the FDA to Mr. Delicato, but attached to that is,
10 I believe -- will you agree attached to that is the
11 May 21, 2008 report that you're referencing?

12 Are we talking about the same document?

13 A. Yes. May 21, Reference 15. This is --
14 Reference 15, Page 8. Well, Reference 15 in my
15 bibliography is an FDA 483.

16 Q. Oh, I'm sorry.

17 A. No. This may be my error and the fact
18 that I had to redo this bibliography in short order
19 because we merged the documents.

20 Q. I -- well, let's -- this exhibit, we can
21 agree, is the EIR from May 21, 2008 inspection;
22 correct?

23 A. Yes.

24 Q. And so you're saying your reference --
25 and, in fairness, Dr. Frank, on the top of Page 3 of

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1 15 of this document, it says, On May 21, 2008, I
2 issued a Form 483 inspectional observations to
3 Mr. Delicato.

4 So it looks like there was a 483 issued
5 that day, and the Establishment Inspection Report, I
6 don't know when it was prepared, but, obviously, there
7 was an inspection that day that resulted in the 483
8 and the generation of this -- the EIR.

9 Would you agree with me there?

10 A. Yes. And there's also May 20th closeout
11 minutes from which they may have been taken.

12 Q. Now, do you know -- well, first of all,
13 can we find -- I'd like to find where you're quoting
14 Mr. Delicato.

15 Would that be in a 483 or would that --

16 A. No. That's why --

17 Q. That's probably going to be in the EIR,
18 isn't it?

19 A. Or in the May 20th closeout minutes.
20 They met with management the day before they issued
21 the 483. There's -- it's May 20th, 2008. And there
22 was some background in there, and I think there was
23 that statement.

24 Q. Can you find -- let's see if you and I
25 can find this statement.

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1 A. I don't know the background of it,
2 that's why it concerned me.

3 MR. THOMPSON: Is it important for us to
4 hunt through, or can I point you all on it?

5 MR. DEAN: Yes, if you've got it. No,
6 show me.

7 MR. THOMPSON: It's on Page 8 of 15,
8 right at the end of that long redaction.

9 MR. DEAN: Thank you, Fred.

10 BY MR. DEAN:

11 Q. Do you see that now?

12 A. Yes. And it was at the closeout meeting
13 that he stated this. I have no information as to the
14 background of that.

15 But there's apparently still unreported
16 cases from January, February of 2006, which seemed
17 unusual because they did aggregate -- they had -- they
18 had --

19 Q. Let me stop you. You're talking about a
20 closeout meeting -- strike that.

21 There was a closeout meeting in regard
22 to Digitek for Actavis Totowa; correct?

23 A. There was an inspection in Actavis
24 Totowa from April 21st to May 25th, and I believe it
25 covered more than Digitek.

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<p>1 I have no way to know whether these</p> <p>2 cases, unreported cases, were Digitek or another</p> <p>3 product or the impact on the Digitek case.</p> <p>4 There's cases that were supposed to be</p> <p>5 part of the remediation. Apparently, they're not</p> <p>6 submitted. I don't know what they are.</p> <p>7 I don't know whether there was</p> <p>8 regulatory risk decision taken by the company. But</p> <p>9 this statement -- am I talking too much?</p> <p>10 Q. No, no. I think we're actually getting</p> <p>11 to the bottom of this. I think we're going to get</p> <p>12 there in a minute.</p> <p>13 So you -- you don't -- first of all, on</p> <p>14 the quote here on the bottom of Page 8, you don't know</p> <p>15 whether any of those related to Digitek, we can agree</p> <p>16 on that?</p> <p>17 A. No.</p> <p>18 Q. Pardon me?</p> <p>19 A. Very little of the information --</p> <p>20 Q. Can we agree on that?</p> <p>21 A. Yes, we agree on that.</p> <p>22 Q. And if you turn the page to Page 9 of</p> <p>23 15, would you agree that there is, again, reference to</p> <p>24 the Denmark site forwarding reports to the Elizabeth</p> <p>25 site and for processing submission to the FDA?</p>	<p>1 Q. -- May 21 inspection of Actavis</p> <p>2 Elizabeth.</p> <p>3 We can agree on that; correct?</p> <p>4 A. Yes.</p> <p>5 Q. And you've already told me you don't</p> <p>6 know whether the events that are being described in</p> <p>7 here are simply related to foreign reporting or not,</p> <p>8 you just don't know one way or another?</p> <p>9 A. Well, the foreign reporting they're</p> <p>10 talking about the July 2006 and August. This is when</p> <p>11 Denmark sent them a bulk of cases. Probably most of</p> <p>12 them should have been in March and April. But I can't</p> <p>13 -- I don't know about the distribution.</p> <p>14 But then they're going back and talking</p> <p>15 about late cases. And there's -- the information in</p> <p>16 here, there may be information in the coding that</p> <p>17 tells -- the case code that tells whether they're a</p> <p>18 foreign report.</p> <p>19 But I don't know enough about the case</p> <p>20 codes to tell.</p> <p>21 Q. And all this -- on Page 8, all this</p> <p>22 really says is that Mr. Delicato said at the closeout</p> <p>23 meeting of the Actavis Elizabeth inspection that they</p> <p>24 did not have a definitive answer as to how far back</p> <p>25 they would go in reviewing unreported cases.</p>
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<p>1 That's what it says, doesn't it?</p> <p>2 A. This is the bulk submission from 2000,</p> <p>3 July and August. That was the implementation of the</p> <p>4 March 1st MHRA agreement. Yes, that is what that is.</p> <p>5 Q. Do you know one way or another whether</p> <p>6 this exhibit and its observations about AERS, do you</p> <p>7 know whether it is solely focused on foreign adverse</p> <p>8 reaction reporting?</p> <p>9 A. If you're talking about B here?</p> <p>10 Q. I'm talking about Exhibit 62. I'm</p> <p>11 talking about the EIR, dated May 21, 2008, submitted</p> <p>12 to Actavis Elizabeth, LLC.</p> <p>13 A. No. I do not know whether this is all</p> <p>14 foreign reporting. I think that --</p> <p>15 Q. Let me ask you this, then. Are you</p> <p>16 aware that there was also, I think, an Establishment</p> <p>17 Inspection Report on Actavis Totowa dated May 20th?</p> <p>18 Have you ever seen that?</p> <p>19 A. Yes. I have those two inspections that</p> <p>20 occurred simultaneously, and I spent a fair amount of</p> <p>21 time sorting between the two of them.</p> <p>22 Q. Okay. But the one you quoted from is --</p> <p>23 the one you quoted from on Page 5 of Mr. Delicato is</p> <p>24 from the --</p> <p>25 A. Yes.</p>	<p>1 It wasn't a submission issue, it was a</p> <p>2 review issue; is that right? Is that the way you read</p> <p>3 it?</p> <p>4 A. Well --</p> <p>5 Q. Take your time. I want to be fair.</p> <p>6 A. There was something else that was left</p> <p>7 outstanding in my mind, and I --</p> <p>8 Q. First -- I want to get to that. But,</p> <p>9 first of all, is it fair to say that this comment</p> <p>10 reflects that everything had been submitted, but there</p> <p>11 was just an issue as to how far back they would go in</p> <p>12 reviewing those cases?</p> <p>13 A. The way he stated it, there were still</p> <p>14 unreported cases outstanding from January and February</p> <p>15 2006. I don't know whether they're foreign. I don't</p> <p>16 know whether they're U.S.</p> <p>17 I don't know whether they were cases</p> <p>18 that were cited in the inspection report or -- there's</p> <p>19 no specifics.</p> <p>20 Q. Okay. All right.</p> <p>21 A. I can't -- I can't state that. And I</p> <p>22 don't know what the how far back means.</p> <p>23 I had an outstanding question in my mind</p> <p>24 that the acquiring company really did not want to put</p> <p>25 resources into remediation of issues that existed</p>

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<p>1 before the time of the acquisition, and they were</p> <p>2 attempting to negotiate this with the health</p> <p>3 authorities.</p> <p>4 If I did not adequately document that in</p> <p>5 my report, I stand corrected. But there was still</p> <p>6 some question in my mind whether they were making</p> <p>7 calculated regulatory risk decisions.</p> <p>8 And that, when he said how far they were</p> <p>9 willing to go back, I can't comment any farther on</p> <p>10 that.</p> <p>11 Q. You don't -- again, this is an area, in</p> <p>12 your mind, where there's missing information; is that</p> <p>13 fair to say?</p> <p>14 Is that yes?</p> <p>15 A. Yes.</p> <p>16 Q. Now, and you are also -- you are unaware</p> <p>17 as to whether subsequent to that comment what follow-</p> <p>18 up there may have been and what the regulatory</p> <p>19 response may have been in regard to that observation;</p> <p>20 is that fair?</p> <p>21 A. I have not seen any subsequent</p> <p>22 documentation to give further insight into these --</p> <p>23 into this.</p> <p>24 Q. So that's more missing information;</p> <p>25 correct?</p>	<p>1 A. I can't tell you whether the</p> <p>2 implementation of the -- of the remediation -- and</p> <p>3 there may be -- there could be blanket statements, and</p> <p>4 I'm just not -- I'm trying to be really accurate here.</p> <p>5 Q. And that's fine.</p> <p>6 A. There could be statements that somebody</p> <p>7 said, yes, it was adequate, but I can't go through</p> <p>8 here quickly and find them.</p> <p>9 Q. And my question is, are these -- I asked</p> <p>10 you whether you were aware of any set of circumstances</p> <p>11 which should have been reported as a MedWatch, which</p> <p>12 wasn't as of this date, and you referenced the later</p> <p>13 observations in the 2008 inspection; right?</p> <p>14 A. They're the ones in which I was</p> <p>15 concerned about.</p> <p>16 Q. If you put those -- if you put those</p> <p>17 aside for the moment because we just talked about</p> <p>18 those --</p> <p>19 A. Yes.</p> <p>20 Q. -- and you already told us you're not</p> <p>21 sure whether those are Digitek or not; right?</p> <p>22 A. Absolutely.</p> <p>23 Q. So put -- so we've explored, I think,</p> <p>24 Exhibit 62.</p> <p>25 So if you put it aside for the moment,</p>
Page 191	Page 193
<p>1 A. Yes.</p> <p>2 Q. Okay. Dr. Frank, as of January 3, 2007</p> <p>3 when Exhibit 87 was issued, are you aware of any</p> <p>4 unreported MedWatch report on Digitek?</p> <p>5 A. There are inspection observations prior</p> <p>6 to that, 2007.</p> <p>7 Q. Listen to my -- listen to my question.</p> <p>8 A. Yes.</p> <p>9 Q. I know that we've talked about issues</p> <p>10 that they had in 2006.</p> <p>11 My question is, as of January 3, 2007,</p> <p>12 are you aware of an unreported MedWatch report in</p> <p>13 regard to Digitek?</p> <p>14 A. That's a very important question, but</p> <p>15 there's a couple different ways to interpret it.</p> <p>16 Q. Well, are you aware of the existence of</p> <p>17 such a report?</p> <p>18 A. I'm aware of unreported cases in the</p> <p>19 initial inspection observations. I'm aware of the</p> <p>20 agreements.</p> <p>21 But I don't have any kind of</p> <p>22 documentation that allows me to track the cases in the</p> <p>23 inspection observations with the remediation and</p> <p>24 submissions.</p> <p>25 Q. So --</p>	<p>1 are you aware of any unreported set of circumstances</p> <p>2 that would give rise -- should have given rise to a</p> <p>3 MedWatch report in regard to Digitek as of January 3,</p> <p>4 2007?</p> <p>5 A. No. The only --</p> <p>6 Q. Was that a --</p> <p>7 A. That was a no. The only observations we</p> <p>8 have are the inspection reports, 2006, and the repeat</p> <p>9 inspection. My information does not allow me to track</p> <p>10 the actions of Actavis in fulfilling the response</p> <p>11 letters.</p> <p>12 Q. So you can't testify, as of any point of</p> <p>13 time after January 2007, that there was a set of</p> <p>14 circumstances that should have been in a MedWatch</p> <p>15 report that was not reported; you just don't have an</p> <p>16 appropriate information base to do that, do you?</p> <p>17 A. There were specific cases in 2008 in</p> <p>18 this. They were Digoxin. I don't know whether they</p> <p>19 were Digitek.</p> <p>20 Q. You don't know?</p> <p>21 A. It's Digoxin, but I think they have some</p> <p>22 sort of XUS Digoxin that I'm not to take into account.</p> <p>23 Q. You are in --</p> <p>24 MR. DEAN: For the record, the witness</p> <p>25 is in Exhibit 62 now.</p>

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1 THE WITNESS: Yes.

2 BY MR. DEAN:

3 Q. And there's reference on what page to
4 Digoxin?

5 A. This is Page 9 out of 15, and there's
6 clearly a Digoxin case there.

7 Q. Right.

8 A. But it's not brand Digitek. And I don't
9 have any -- I didn't get any written documentation
10 that -- I know they have from the -- from some of the
11 other depositions, they have XUS Digoxin, but it's not
12 Digitek.

13 And I repeatedly clarified whether XUS
14 cases should be brought into this assessment, and I've
15 been told no. Okay.

16 Q. And just for the purposes of time here,
17 you don't know whether this reference on Page 9 of 15,
18 whether that reference to Digoxin tablets references
19 Digitek or not, do you?

20 A. No. We need to know this case number.
21 That will code the country of origin of the case.

22 So it is possible to tell whether that's
23 a U.S. case that was just reported as the generic and
24 should be taken into account, or whether it's
25 potentially an XUS case.

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1 Q. So, as you sit here today, you're not
2 aware of any -- you don't have any specific facts that
3 there was a set of circumstances in regard to Digitek
4 after January 3, 2007, which was not appropriately
5 reported in a MedWatch; is that correct?

6 A. The only thing that I have are these
7 inspection reports.

8 Q. Being --

9 A. And my answer at this point, my
10 preliminary answer is, no, I cannot identify it from
11 memory.

12 Q. Let's go on to another topic here.

13 Are you done with that one? Yes, let's
14 get those out of your way.

15 A. Okay.

16 Q. One of the topics you address in your
17 report is the -- what I will call the recall
18 communications.

19 A. I was asked to specifically look at
20 those and the change in the patient population at
21 risk.

22 And I was provided the attorney's
23 initial assessment that from the -- from the Health
24 Hazard Assessment to the letter to the customers to --
25 which are the business customers, which is Mylan, to

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1 the press releases to the public, there was a change
2 in risk population.

3 I brought up the issue that at least in
4 writing informed consents in clinical trials, we write
5 to a fourth- to fifth-grade comprehension level.

6 And that when they wrote the press
7 release, there may have been that process to modify
8 the communication. I did not put that in my report.

9 But what I did was, I tracked the
10 changes in patient population, which did change from
11 the Health Hazard Assessment to the final
12 communication, and the changes in the patient
13 population at risk, and I commented on that.

14 I was asked to comment, and I thought
15 there was clearly a change and it clearly changed the
16 total patient population that would be warned. And
17 that's pretty carefully documented, those changes with
18 quotes.

19 I did not speculate on why it was done,
20 on any data that would have supported the removal,
21 because I had no access to that.

22 But they did go from a larger patient
23 population at risk to a smaller patient population at
24 risk by the time they released the press release.

25 Q. Okay. First of all, would you agree in

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1 terms of the recall communication, it was clear to
2 everyone that the company wanted the product back and
3 off the market and no one should be taking it?

4 A. Yes.

5 Q. Okay.

6 A. A recall is a recall.

7 Q. Right.

8 So anyone who, whether they were a
9 patient, a pharmacist, a doctor, they would have
10 gotten that message; correct?

11 A. Yes.

12 Q. Okay.

13 A. With patients.

14 Q. Now -- were you finished?

15 A. Well, yes. If you hear about a recall
16 drug, it's a recall drug.

17 Q. All right. Fair enough.

18 A. The people who are -- a recall drug is a
19 recall drug, but there's a change in the level of
20 alarm. To some patient populations, it was
21 downplayed. It was removed. But a recall is a
22 recall.

23 Q. All right. So then would you also
24 agree, from your experience with the FDA, that the FDA
25 approved all recall communications before they were

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1 issued?

2 Would you agree with that?

3 A. The FDA inspectors were very, very
4 concerned about not having received final copies of
5 the recall letters.

6 Q. Well, my question is, before these
7 letters went out to the various recipients, is it your
8 understanding -- and maybe you don't have an
9 understanding, but my question to you is, is it your
10 understanding that the FDA would have approved the
11 substance, not just the substance, would have approved
12 in its entirety the press release, the communication
13 to pharmacies, the communication -- any communication
14 that was sent out about the recall?

15 Is it your understanding the FDA would
16 have approved that?

17 A. Yes.

18 Q. Okay. Now, you --

19 A. I hope that that actually did occur in
20 this case, but I can't -- perhaps I should have gone
21 back in a very detailed analysis, but I don't think
22 there is.

23 I think there was a concern about the
24 delay in the recall procedures and the delay in
25 providing final reports. But, yes, the FDA should

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1 have approved what was released.

2 (Discussion off the record.)

3 THE WITNESS: It would be in the May
4 20th meeting closeout. I'm pretty sure it was the
5 meeting closeout --

6 MR. DEAN: Thank you.

7 THE WITNESS: -- because they became --

8 MR. THOMPSON: This is mine. You gave
9 this to me.

10 MR. DEAN: You keep it.

11 MR. THOMPSON: I'm happy to put it back
12 into play, but I don't want to be accused of
13 swallowing a copy.

14 BY MR. DEAN:

15 Q. Your criticism on the difference in the
16 communication of information about various groups is
17 set out in your report, is that right, on the recall
18 communication?

19 A. Yes.

20 Q. Do you remember the substance of that --
21 of that?

22 A. It's in this document. I mean, I was
23 asked specifically to comment on certain issues,
24 particularly the change in renal insufficiency to
25 renal failure.

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1 And that's where I made the question
2 that that could be an artifact of the review of
3 something being written to a fourth- to fifth-grade
4 level.

5 I don't know about press releases to the
6 general public, whether they have the same
7 requirements as the informed consent to clinical
8 trial.

9 So we talked about that with the renal
10 insufficiency. We talked about the removal of the
11 once daily dosing.

12 And then I brought up the third change
13 in the -- in the press release, because the Health
14 Hazard Assessment said lack of efficacy with
15 exacerbation, and that was omitted.

16 So there were three changes, daily
17 dosing, renal insufficiency and lack of efficacy were
18 distilled down to renal failure.

19 Yes, you're correct, that could have
20 been done in negotiations with the FDA. In light --
21 in light of that FDA document that says there was no
22 risk to public health, there may be background to
23 this.

24 But there were three changes. And it
25 does change the direct communication to the patient

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1 population at risk.

2 Q. Let me hand you what we marked as 37.

3 A. Okay.

4 MR. DEAN: Fred.

5 BY MR. DEAN:

6 Q. Have you ever -- have you seen Exhibit
7 37 before?

8 A. Yes.

9 Q. Okay.

10 A. This was -- this was the basis on which
11 I tracked -- I was asked to track the changes and
12 comment whether there were change in the populations
13 described from one communication to the next.

14 Q. And one of these communications went out
15 on April 25th; is that right?

16 A. Yes.

17 Q. And can you direct us to that?

18 A. That's 28213. That's the press release.

19 Q. And is it your understanding that that
20 was issued on April 25?

21 A. Yes.

22 Q. And --

23 A. I cannot comment at this point in time
24 the relationship between this release and the FDA
25 approval or any impact of the FDA review on the

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1 changes.
 2 Q. Now, your point is, if I understand, the
 3 point -- the basic point in your report is that on
 4 this April 25 press release, it mentioned a renal
 5 failure, and several days later different
 6 communication was conveyed to pharmacies; is that
 7 correct?
 8 A. Well --
 9 Q. Is that one of your basic points?
 10 A. I have this packet of communications.
 11 Q. Right.
 12 A. I have nothing else. When one stops a
 13 clinical trial such as the WHI, there are letters that
 14 go out to the doctors, the patients, the study
 15 coordinators.
 16 I do not know whether that is a standard
 17 in a drug recall like this. These are two different
 18 situations.
 19 Q. Right.
 20 A. But I don't have any letters directly to
 21 patients or directly to doctors. I have only this.
 22 Q. Okay.
 23 A. I have a Health Hazard Assessment, I
 24 have a communication to Mylan, which never, to my
 25 knowledge, reached the public except in this exhibit,

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1 and then there's a press release that went out.
 2 So I was asked specifically to comment
 3 on the changes from A to B to C, and what the patients
 4 and the doctors saw as far as the scope of the risk of
 5 the defect. I agree with you that a recall is a
 6 recall.
 7 Q. Okay. So --
 8 A. But there was granularity omitted from
 9 the press release and the question is why.
 10 Q. Right.
 11 And so when you said A to B to C, A
 12 would be -- the first thing in the sequence would be
 13 the press release on April 25; right?
 14 And then what is B and C in terms of
 15 your last answer?
 16 A. The press release was on the 28th. The
 17 internal communication to Mylan was on --
 18 Q. Excuse me. The press -- or the news
 19 release --
 20 A. I'm sorry. The Health Hazard Assessment
 21 was the 28th. Is -- no, the 18th. The Health Hazard
 22 Assessment was the 18th. I think it was sent over on
 23 the 25th. The cover letter was the 25th.
 24 Q. Okay.
 25 A. The press release was also on the 25th.

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1 Q. Right.
 2 And then --
 3 A. And then the internal letter went out
 4 subsequently. Now, I would have -- I don't know about
 5 the receipt date. I think the cover letter -- you can
 6 check the cover letter on the Health Hazard
 7 Assessment.
 8 Q. We will in a minute.
 9 What was the follow-up -- there was a
 10 follow-up letter that I think you referenced in your
 11 report after the press release. Was it the Dear
 12 Valued Customer letter?
 13 A. That's the 28th. That's an internal
 14 communication.
 15 Q. What's the Bates number page there,
 16 Dr. Frank?
 17 A. It's 28208.
 18 Q. So in the April 25 press release, it
 19 simply references renal failure.
 20 But in the April 28 Dear Valued Customer
 21 letter, it talks about patients taking daily doses or
 22 patients with renal insufficiency; correct?
 23 A. Yes.
 24 Q. And you believe that's more detailed
 25 information that was not contained in the press

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1 release; correct?
 2 A. Well, it is more detailed. But it
 3 changes the population at risk. So the press release
 4 -- and this is where I was -- I was asked to comment
 5 on certain things.
 6 I was asked to analyze evidence to
 7 support two observations when I was asked to do this.
 8 One was the systemic issues of
 9 pharmacovigilance on signal detection and the other
 10 are these changes from one to the next. And that's
 11 what I did.
 12 I'll admit, this wasn't sequential.
 13 This actually was a later date than the press
 14 release. I will -- yes, you're correct on that.
 15 Q. Which is -- which is -- what date is on
 16 that?
 17 A. This is the Dear Valued Customer.
 18 Q. Right.
 19 A. And I questioned what the customer was,
 20 and I was told that was internal. That did not go out
 21 to the patients, to my knowledge.
 22 Q. And so what you're suggesting is, I
 23 think, that the company had information on April 25
 24 that it didn't put in the press release that it did
 25 put in the April 28 letter; is that correct?

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<p>1 A. Yes. The internal communications show a 2 broader patient population at risk than the 3 communication to the public. 4 Q. And you said that while the -- before 5 you mentioned that while the Health Hazard Evaluation 6 report was done on April the 18th, you said it -- I 7 think you said you were right that it was transmitted 8 on April the 25th; correct? 9 Is that your recollection? 10 A. There should be a cover letter. And, as 11 I recall, it's the 25th, and I went, why did it take 12 so long to transmit something that was written on the 13 18th? But the April 18th is something I reiterated in 14 the document. 15 Q. Well, your memory is actually very good, 16 Doctor. 17 I'm putting in front of you Exhibit 18 220 -- 19 A. Yes. 20 Q. -- which is that cover letter from 21 Dr. Leikin's group to Sarita Thapar; correct? 22 A. Uh-huh. 23 Q. And it's dated April the 25th; correct? 24 A. Yes. 25 Q. And can you -- and for the record, how</p>	<p>1 (Witness reviews document.) It has 2 toxicity -- daily doses or renal insufficiency, and it 3 contains the lack of efficacy. Yes, I think this one 4 tracked verbatim to the Health Hazard Assessment. 5 Q. So this, the Dear Valued Customer 6 letter, tracked the information contained in the 7 Health Hazard Evaluation report that was transmitted 8 to Actavis on April 25 by Federal Express; correct? 9 A. Yes. 10 Q. Okay. But you didn't -- when you were 11 doing your review, you didn't link that up in your 12 mind, did you? 13 A. I think I was operating on the 14 assumption that that press release was made after 15 receipt of the Health Hazard Assessment or 16 communication of what was in the Health Hazard 17 Assessment. 18 And that may have been because I made 19 assumptions that I -- when I received this assignment, 20 I was asked to reply on a series. And I did not go 21 back. 22 I looked at these dates and I wondered 23 why that cover letter was dated the 18th, during -- 24 the 25th and why the Health Hazard Assessment was the 25 18th, but I didn't go back and verify this. I -- and</p>
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<p>1 was that letter sent? 2 A. Overnight Federal Express. So it 3 arrived on the 26th. 4 Q. So it arrived on the 26th; correct? 5 A. Yes. 6 Q. So on April the 25th, when the press 7 release was issued, the information in the Health 8 Hazard Evaluation had not been received, had it? 9 A. Unless there was an additional faxed 10 copy and this was the follow-up hard copy. 11 Q. And -- but you -- again, that's an area 12 where you don't have information; correct? 13 A. No. And I did not -- I knew that letter 14 was the 25th, but I -- I did not connect the fact that 15 the press release went out the day before that would 16 have been received if that was the only copy. 17 Q. And can we also agree that in the Dear 18 Valued Customer letter, the information in here about 19 the two groups, about the daily dosage group and the 20 renal insufficiency group, that is contained in the 21 Dear Valued Customer letter on the 28th, isn't it? 22 A. I need to look at this again before I 23 answer. 24 Q. Sure. Take your time. It's 28208. 25 A. 28208.</p>	<p>1 I don't know. 2 They may have issued the press release 3 before they got the Health Hazard Assessment based on 4 some sort of a preliminary analysis. Perhaps that 5 company internal document that I have not seen. 6 Q. But from what you have seen and what we 7 have in front of us, anyway, today, when they issued 8 the press release on the 25th, they would not have had 9 the Health Hazard Evaluation; correct? 10 A. Unless there was a copy faxed in 11 followed by the FedEx. 12 Q. Okay. 13 A. I actually -- I do not have 14 documentation of what the supporting documents were 15 for that press release. 16 The assumption was that the Health 17 Hazard Assessment from the 18th would have been 18 wrapped up into external communication for just these 19 issues. 20 But that -- that cover letter does beg 21 the question because it would have been received one 22 day after the press release. 23 Q. At the bottom of Page 6 -- I'm back on 24 Exhibit 261, Dr. Frank. 25 The bottom of Page 6 there is a -- the</p>

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<p>1 second sentence says there was a notable absence -- I 2 think you left out the word "of" -- absence of 3 oversight from a centralized headquarters function in 4 Iceland to track local compliance and exchange of 5 information between the U.S. and the EU affiliates. 6 What is the basis for that opinion? 7 A. Okay. 8 Q. First of all, what documentary -- what 9 documents do you have that are even relevant to that 10 issue? 11 Let's talk about that first. 12 A. That's why there's an absence. 13 One of the things the health authorities 14 do in these drug withdrawal cases, for new adverse 15 events, say liver failure or torsade, if the health 16 authority identifies the issue before the company, 17 they go back to the company and say, why are we 18 telling you about a serious safety problem with your 19 drug? 20 The assumption is that the company 21 should have processes in place to identify the issue 22 first, and then go back and tell the health authority 23 it exists, and then the issue starts into a dialogue 24 of whether this drug has to come off the market. 25 This is conventional wisdom. And I</p>	<p>1 stockpiling reports and sending them in July and 2 August when the implementation date on that MHRA 3 agreement was March 1st. 4 That could have easily been picked up by 5 tracking those dates, those submission dates. 6 And so the question comes up, and this 7 is -- this is, again, extrapolating from other cases 8 where the authorities come back and say to the 9 company, why are we telling you about these issues? 10 Q. Well, let's stop. First of all, it 11 sounds like you raised with the plaintiffs' lawyers 12 the issue as to whether you had expertise to even 13 comment about this issue; is that fair? 14 A. Well, we talked about scope, and I'm 15 talking about systems. And this is on the edge of 16 those systems because I have some experience. I've 17 never done a merger integration. 18 I was involved with Roche headquarters 19 drug safety reorganization, which was clearly a 20 headquarters reorg. where there was centralization of 21 procedures that had been decentralized, gone out of 22 compliance. 23 And it's the centralization and 24 headquarters oversight that has frequently been 25 critical in these multinationals that have compliance</p>
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<p>1 didn't -- I don't want to document the cases where 2 this occurred. 3 But when I've worked at headquarters, 4 these international companies typically are 5 headquarters holding companies, and each country level 6 affiliate is an independent company under the holding 7 company, and they operate in conjunction with local 8 regulations. 9 Headquarters typically tracks compliance 10 at the local level. But the responsibility is there. 11 But there's a growing movement toward 12 tracking this data, spidering this data from local 13 departments onto dashboards of managers. 14 And so the issue here -- and I talked to 15 them, this is somewhat outside of my expertise, but my 16 question is, I was given no evidence that headquarters 17 identified these noncompliance issues before the FDA 18 2008 inspection. 19 So the remediation was to do new 20 processes, to move things to Elizabeth, to make a 21 provision that Copenhagen would send cases to the U.S. 22 But I have no evidence that headquarters 23 was actually -- had a strong governance function over 24 the individual compliance. 25 They didn't realize that Copenhagen was</p>	<p>1 issues with safety, not just with Roche, but with 2 other companies. 3 Q. Did you tell the plaintiffs' counsel in 4 this case this was outside your area of expertise? 5 A. I asked if they thought it was and 6 whether I should take it out and they were pleased 7 with that being left in the document. 8 Q. But you, yourself, raised the question 9 as to whether it was outside your area of expertise; 10 correct? 11 That's what I hear you saying. I want 12 to make sure I understand you correctly. 13 A. Well, this is my first time as an expert 14 witness, and I'm trying to determine what scope of 15 pharmacovigilance systems is. This is -- this is 16 technically within the scope of -- 17 Q. I know. My question was -- I'm sorry. 18 A. It may be, but I can't give you a 19 definitive answer. 20 Q. My question was very simple. Did you 21 tell the plaintiffs' attorneys this was outside your 22 area of expertise? 23 A. It was possibly. 24 Q. Okay. Now, you don't know how Actavis 25 in Iceland was set up structurally to interact with</p>

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1 Actavis in the United States, do you?

2 A. No. We were not given any information

3 as to the headquarters function and overseeing their

4 affiliates or how much headquarters was initially

5 involved with the 2006 inspection, other than to

6 ratify the decision at the time of the acquisition to

7 implement the MHRA agreement between the two.

8 Q. Is it fair to say you have insufficient

9 information to be able to comment on the oversight

10 responsibilities of headquarters in Iceland in regard

11 to local pharmacovigilance issues?

12 A. These may have been placed. I was not

13 given any information to say that there were. And I

14 don't -- I don't know I do.

15 I know that they wanted -- when they got

16 the first inspection, the initial fix was to move the

17 processes to Actavis.

18 There's not a lot of insight into the

19 process of transfer or any other process changes at

20 the time of the acquisition and the merger of some of

21 these acquisition companies.

22 I guess, there is -- there's an absence

23 of insight into what happened. There's no assurance.

24 Q. Do you consider yourself to be an expert

25 in the issue of recall communications?

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1 A. Honestly, no.

2 Q. Okay.

3 A. I can't say that I've done a huge number

4 of them.

5 Q. Okay. And I think we established before

6 that what you did in regard to recalls was maybe do

7 the Health Hazard Evaluation reports. But you've

8 never participated in drafting the recall documents

9 themselves; correct?

10 A. No. My role has been to draft the

11 assessment -- my role has been to draft the

12 assessments. And sometimes I sit on the

13 multifunctional team.

14 But once the decision is made to recall

15 or to try to obtain product for analysis, typically,

16 any recall communications go out of a different

17 office.

18 MR. DEAN: All right. Let's take a

19 short break.

20 VIDEO OPERATOR: Going off the video

21 record.

22 The time is 3:19 p.m.

23 (A recess was taken from 3:19 p.m. to

24 3:30 p.m.)

25 VIDEO OPERATOR: We're now back on the

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1 video record.

2 The time is 3:30 p.m.

3 BY MR. DEAN:

4 Q. Do you have any criticisms of the

5 information gathering process for information that

6 would go into a MedWatch report by Actavis before the

7 time of the recall?

8 A. There are inspection observations from

9 the inspection of January 2006 that there was

10 inadequate information in the cases and inadequate

11 follow-up, and they cited several cases.

12 So they were looking at the content of

13 information, things that were absent, such as

14 concomitant medications and concurrent diseases, as

15 well as follow-up issues, particularly on a death

16 case.

17 Q. Are you aware of any -- let me reframe

18 my question in point of time. Same question, but

19 after January 3, 2007, when the letter that we saw was

20 issued.

21 And so after January 3, 2007, are you

22 aware of any criticism -- and before the recall, in

23 that time frame from January '07 to end of April, '08,

24 are you aware of any criticisms of the information

25 gathering process by which Actavis gathered

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1 information to generate MedWatch reports?

2 A. No.

3 Q. Okay. Did you ever say to the

4 plaintiffs' attorneys in this case that I cannot in

5 good conscience give an expert report in this

6 litigation because I am concerned that I don't have

7 all the potentially relevant documents?

8 A. I said I do not think I can render a

9 definitive opinion. I can only give opinion on the

10 evidence to which I was -- on which I was presented.

11 And I talked to them about what if I

12 render an opinion that's inadequate based on

13 inadequate evidence? And they encouraged me to render

14 the best opinion that I could based on the evidence

15 that I was presented.

16 They presented me with some more

17 evidence, and I did the best I could with what I was

18 given.

19 And I knew that there were

20 vulnerabilities that remained based on white space,

21 but there was -- there was -- the original report was

22 written with more statements of no assurances

23 provided, no information is provided.

24 There was more of a statement of the

25 absence.

55 (Pages 214 to 217)

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<p>1 I was asked to rephrase things to say,</p> <p>2 my opinion based on reasonable evidence, and I did</p> <p>3 that on June 15th.</p> <p>4 So there was a report written that was</p> <p>5 -- with language where I would be presenting this to a</p> <p>6 client based on a consulting firm.</p> <p>7 And I was given some guidance on how to</p> <p>8 rephrase the report, and I went in and I rephrased the</p> <p>9 report where I thought there was FDA inspection</p> <p>10 observations that would fit together as reasonable</p> <p>11 evidence, such as I keep repeating, the fact that 2008</p> <p>12 still had inspection findings.</p> <p>13 It was a question of nonsubmission of</p> <p>14 cases. There were things like that that became the</p> <p>15 basis.</p> <p>16 But I actually trusted them that they</p> <p>17 were providing me enough information that it was</p> <p>18 conscionable to form those positions.</p> <p>19 They reviewed them and they reviewed the</p> <p>20 final wording, and I trusted their counsel that this</p> <p>21 report, although preliminary and possibly requiring</p> <p>22 revision, was suitable for filing.</p> <p>23 Q. Now, did you just tell me that there is</p> <p>24 a -- I guess it would be on one of these thumb</p> <p>25 drives -- that there is an initial report that you</p>	<p>1 conscience that you might be rendering an opinion</p> <p>2 without appropriate foundation?</p> <p>3 Was that what you meant to convey by</p> <p>4 your use of the word "conscionable"?</p> <p>5 MR. THOMPSON: Object to the form.</p> <p>6 THE WITNESS: I'm completely naive to</p> <p>7 this. I've avoided this for eight years and I was</p> <p>8 encouraged to write this report based on people who</p> <p>9 had worked with me who felt that I was qualified to</p> <p>10 start to take on this kind of work.</p> <p>11 I have no way to independently judge my</p> <p>12 ability to serve as an expert witness. And I don't</p> <p>13 know whether this is the type of case where you start</p> <p>14 expert witness.</p> <p>15 I trusted the attorneys who provided me</p> <p>16 with information to give me the information that I</p> <p>17 needed to determine what was going on.</p> <p>18 I went back to them with questions and I</p> <p>19 did ask about the process of discovery and why there</p> <p>20 were all these things that I was not provided and</p> <p>21 would they be provided to me. And I talked to them</p> <p>22 about what do I do with this information?</p> <p>23 And they -- she said -- based on that, I</p> <p>24 believe that it was okay to render the preliminary</p> <p>25 report. I did this on advice of counsel and with the</p>
Page 219	Page 221
<p>1 wrote and then there's a follow-up report that you</p> <p>2 wrote after you had expressed concerns to the</p> <p>3 plaintiffs' counsel about what you'd said in your</p> <p>4 report?</p> <p>5 Did I get that correctly?</p> <p>6 A. No. I was very, very careful about</p> <p>7 making too many preliminary comments. I spent an</p> <p>8 awful lot of time trying to gather and organize the</p> <p>9 information and track it.</p> <p>10 I probably started tracking quality</p> <p>11 information from manufacturing and trying to assess</p> <p>12 whether the quality systems were impacting</p> <p>13 pharmacovigilance. I probably went on a tangent.</p> <p>14 But, no, there was no real preliminary</p> <p>15 report that I revised. I did the report and I was</p> <p>16 asked to change the wording to the legal wording</p> <p>17 required for an expert report.</p> <p>18 Q. Now, is the backup to what you just said</p> <p>19 where you were -- where you made changes in the</p> <p>20 wording, is that someplace on the thumb drive?</p> <p>21 A. I don't know whether I overwrote it. I</p> <p>22 think there are early drafts.</p> <p>23 Q. You used the word "conscionable" a few</p> <p>24 minutes ago.</p> <p>25 Were you worried as a matter of your</p>	<p>1 supervision of counsel.</p> <p>2 But knowing that there could be further</p> <p>3 information that may or may not have been already</p> <p>4 uncovered with discovery.</p> <p>5 And I was told that it is okay to render</p> <p>6 this preliminary opinion. If they present you with</p> <p>7 further evidence, you go back and revise it.</p> <p>8 BY MR. DEAN:</p> <p>9 Q. Is it fair to say that based upon what</p> <p>10 you've seen today, you are no longer comfortable and</p> <p>11 you do not stand fully behind this opinion?</p> <p>12 A. I would say yes. My preference would be</p> <p>13 to, as I was told I could do, incorporate new</p> <p>14 information.</p> <p>15 But -- but, yes, there -- I -- I think</p> <p>16 that there has to be -- there should be re-analysis of</p> <p>17 that opinion based on further information. And maybe</p> <p>18 even some of the information that's not yet presented.</p> <p>19 Q. So is it fair to say that as from your</p> <p>20 -- with your medical training and your background in</p> <p>21 the FDA, you, yourself, think that there is an</p> <p>22 inadequate foundation for your opinion in this report;</p> <p>23 correct?</p> <p>24 A. I don't have an answer to that. I feel</p> <p>25 -- Mr. Thompson encouraged me at the break to say,</p>

56 (Pages 218 to 221)

Karen A. Frank, M.D.

Videotaped

June 30, 2010

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<p>1 well, you're as much an expert on this as anyone else. 2 I have no way to compare myself to 3 anyone else. I've never even witnessed court 4 proceedings. I deliberately avoided getting involved 5 with litigation. It's not like I've been aiming at 6 this. 7 This is something that I was approached 8 about doing a couple times and sort of said, no, no, 9 no, I'm not going to be involved with that. 10 And I was approached about taking this 11 assignment and very carefully working on it. I asked 12 about the documentation. 13 And I had to trust the people who had 14 hired me that I was being given correct guidance so 15 that this would be a useful piece of information and a 16 viable one, but I have no way to independently judge 17 that. 18 If -- I should have said, I cannot write 19 this report until I am given all of this, I was given 20 assurance that I'm to render a preliminary opinion 21 based on what was given me. 22 Q. So it was your understanding that what 23 was submitted to the Court was just a preliminary 24 report, then; is that right? 25 A. It was my understanding that these</p>	<p>1 A. I don't recall. I don't recall whether 2 I -- 3 Q. Is that the -- 4 A. I don't recall whether I pressed him on 5 how far I should extend out. I know they've 6 encouraged me several times not to go outside of the 7 scope of my assignment in making comments. 8 But that statement was included in the 9 conclusion with Mr. Miller's approval. 10 Q. How do you think all this impacts on 11 your credibility, Dr. Frank? 12 A. I think it demonstrates a very 13 legitimate attempt to do a decent job with suboptimal 14 information. If I did not know to refuse to render an 15 opinion, then I wish I had been informed by the 16 counsel. 17 But I think it demonstrates my ability 18 to analyze the quality of the evidence and to define 19 things that could potentially be missing. Some of the 20 things that you presented to me I would not have known 21 to even have asked for. 22 But I raised the issue of whether or not 23 these opinions should be rendered on a series of 24 evidence, and I was given no indication that this was 25 unconscionable or would be seen to jeopardize my</p>
Page 223	Page 225
<p>1 opinions were to be based on observations that I could 2 make based on the present state of the evidence 3 provided to me. I was asked not to say anything 4 speculative. 5 I asked Pete Miller specifically about 6 this comment about the headquarters oversight, and he 7 liked that comment. He did not ask for it to be 8 written. 9 But I asked, I said, is this -- I don't 10 know -- I can't give you the exact wording, but I 11 wanted to make sure I didn't go out of the scope. 12 But I was extrapolating these 13 pharmacovigilance systems which usually go into a 14 headquarters oversight. 15 And he particularly liked that section 16 of the report, and I was given no indication that the 17 inclusion of those statements would be a problem. He 18 approved them. 19 Q. So I understand that particular 20 exchange, you raised the question about your expertise 21 to give an opinion in that area, and Mr. Miller's 22 response was, I like that opinion. Let's leave it in. 23 That was the conversation; correct? 24 A. I don't recall the specifics. 25 Q. Is that the --</p>	<p>1 credibility. 2 It may display a learning curve. It may 3 display a naivete at dealing with certain things. But 4 I was never once given any indication that this was 5 unconscionable or unethical behavior. 6 Even though I questioned, I wanted to 7 make sure that none of this was done, and we discussed 8 it on June 2nd. This is a pretty complex case. 9 There's a lot of stuff that was not -- 10 was not -- I don't know -- I don't know whether it 11 should or should not have been prepared for me, 12 whether it was incumbent upon me to go find the 13 additional information. 14 I asked for more. Or whether I should 15 have quietly made a determination on the first 16 dossier. 17 Q. But we can agree, in your words that you 18 uttered two minutes ago, that the information you had 19 here on which to base your opinion was suboptimal; 20 correct? 21 A. Yes. It was suboptimal. There's -- 22 there was probably a lot more information out there 23 that was not present. 24 Q. And information which might well lead 25 you to change your opinion; correct?</p>

57 (Pages 222 to 225)

Karen A. Frank, M.D.

Videotaped

June 30, 2010

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<p>1 A. Modify the opinion, yes.</p> <p>2 MR. DEAN: Let's end this tape.</p> <p>3 VIDEO OPERATOR: Going off the video</p> <p>4 record.</p> <p>5 This is the end of Tape 4.</p> <p>6 The time is 3:46 p.m.</p> <p>7 (A recess was taken from 3:46 p.m. to</p> <p>8 3:50 p.m.)</p> <p>9 VIDEO OPERATOR: We are now back on the</p> <p>10 video record.</p> <p>11 This is the start of Tape 5.</p> <p>12 The time is 3:52 p.m.</p> <p>13 BY MR. DEAN:</p> <p>14 Q. Dr. Frank, do you realize that there's a</p> <p>15 lot of money at stake in this litigation?</p> <p>16 A. Yes.</p> <p>17 Q. And do you realize there are</p> <p>18 Court-imposed deadlines for all of us, expert</p> <p>19 witnesses and lawyers?</p> <p>20 Do you realize that?</p> <p>21 A. Yes.</p> <p>22 Q. Were you led to believe that this report</p> <p>23 that you were going to -- that you have submitted was</p> <p>24 only a preliminary report?</p> <p>25 Was that the indication that you were</p>	<p>1 and I examine what you said -- give me very carefully</p> <p>2 is I realize there's a lot at stake. And I want to be</p> <p>3 careful to do the right thing.</p> <p>4 I was -- I thought that I was being</p> <p>5 careful enough. And he wants me to stand by what I've</p> <p>6 written.</p> <p>7 Q. Were you --</p> <p>8 A. I'm -- I'm sort of like, this is the</p> <p>9 first time I've done it, I want to make sure that it's</p> <p>10 done absolutely correctly.</p> <p>11 And yet, I can tell you right now that I</p> <p>12 started going through this and going, well, I mean, I</p> <p>13 can tell you that there was other information that</p> <p>14 would have given indication of the compliance.</p> <p>15 But I said, well, they still had</p> <p>16 inspection findings in 2008. That probably indicates</p> <p>17 inadequate implementation of the plans.</p> <p>18 So I've been -- I've sort of been</p> <p>19 encouraged to, even though I may be naive and a little</p> <p>20 bit insecure in what I'm doing, stand by this.</p> <p>21 Now, I just -- I just don't want to do</p> <p>22 anything wrong. I did the best I could with what I</p> <p>23 was given, and I worked under the guidance of my</p> <p>24 client.</p> <p>25 Q. Your client being the plaintiffs'</p>
Page 227	Page 229
<p>1 given?</p> <p>2 A. I'm afraid so.</p> <p>3 Not -- the word "preliminary" was not</p> <p>4 used, but I was led to believe that there would not be</p> <p>5 any question or problem writing this in this way, and</p> <p>6 that if I was presented with additional evidence, I</p> <p>7 was to modify this.</p> <p>8 And I -- Mr. Thompson is concerned that</p> <p>9 I've suddenly backed away from my report because I've</p> <p>10 been presented with two pieces of evidence.</p> <p>11 I'm sorry, maybe I'm just frightened. I</p> <p>12 don't want to do anything wrong. And maybe I need</p> <p>13 more assurance than the average person.</p> <p>14 But, yes, I did realize there was a</p> <p>15 deadline. I was a little amazed when I found out that</p> <p>16 this was actually going to be a big federal case. I</p> <p>17 thought it was a rather small assignment. But he's</p> <p>18 concerned that I backed down too quickly.</p> <p>19 I don't know how to gauge accurately</p> <p>20 what is sufficient information to render -- completely</p> <p>21 render opinion.</p> <p>22 I may have -- I asked many people</p> <p>23 whether I was qualified to do this as an expert</p> <p>24 witness. He's asked me to stand by what I said.</p> <p>25 But, yes, one of the reasons I sit here</p>	<p>1 lawyers; correct?</p> <p>2 A. Knowing that you would come with further</p> <p>3 evidence. And how I should respond, he said, well,</p> <p>4 look, you're backing down. You've been shown two</p> <p>5 additional pieces of evidence. Is that enough to sway</p> <p>6 your whole opinion?</p> <p>7 I'm sitting here, well, I guess I'd like</p> <p>8 to do another careful analysis. But he's encouraging</p> <p>9 me to stand by my opinion.</p> <p>10 Q. What I'm interested in is whether you</p> <p>11 are willing to stand by it given what you have seen</p> <p>12 today.</p> <p>13 And I get the impression that you are --</p> <p>14 you don't think that there is a sufficient -- I get</p> <p>15 the impression you think there's not sufficient</p> <p>16 information base for you to continue to stand by this</p> <p>17 opinion.</p> <p>18 Am I correct in that impression?</p> <p>19 A. I actually don't know how to answer you.</p> <p>20 Q. You can't unequivocally stand behind the</p> <p>21 opinion that you have written, can you?</p> <p>22 A. No.</p> <p>23 Q. Okay.</p> <p>24 A. But I don't know that it should be</p> <p>25 discarded.</p>

58 (Pages 226 to 229)

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<p>1 Q. You said that --</p> <p>2 A. I actually was under the impression that</p> <p>3 if I was presented additional information, I was to</p> <p>4 modify the position to accuracy and that there would</p> <p>5 be no problems whatsoever in taking this course.</p> <p>6 Q. You told me a few minutes ago that there</p> <p>7 was other information that you had that would have led</p> <p>8 to the conclusion of compliance with appropriate</p> <p>9 procedures, but you did not put it in your report.</p> <p>10 Why didn't you put it in your report?</p> <p>11 A. Can you tell me what I omitted? Can you</p> <p>12 give me the specifics of what I said?</p> <p>13 Q. I'm just referencing what you said a few</p> <p>14 minutes ago, that there were -- if necessary, we could</p> <p>15 have the court reporter read your answer back.</p> <p>16 But I believe you said that there were</p> <p>17 -- there's other information that was available that</p> <p>18 would have aided the defendants -- that's not quite</p> <p>19 the way you phrased it -- but there's other</p> <p>20 information that would have led to a different</p> <p>21 conclusion but you left it out of your report.</p> <p>22 Do you remember saying that?</p> <p>23 A. No. I never deliberately omitted any</p> <p>24 opinion -- any evidence that would have swayed the</p> <p>25 opinion in the direction of the defendants. There was</p>	<p>1 information about product complaints. Could you tell</p> <p>2 me what -- if you can find it, what page you're</p> <p>3 referencing, Dr. Frank.</p> <p>4 If you can't find it readily, that's</p> <p>5 okay, just tell me. But if you can find it, I'd like</p> <p>6 to look at that page. I realize there's a lot of</p> <p>7 pages.</p> <p>8 A. No, I think it's important because I</p> <p>9 tried to find both. I tried to find as much</p> <p>10 information as I could.</p> <p>11 (Witness reviews document.) I saw it a</p> <p>12 while back.</p> <p>13 (Witness reviews document.)</p> <p>14 Q. Let me do this. Let me see if I</p> <p>15 properly understood your reference, and if I did,</p> <p>16 maybe we don't need to find it.</p> <p>17 I think what you said was there was some</p> <p>18 information that you picked up and referred to in the</p> <p>19 observations about product complaint information that</p> <p>20 was appropriately reported.</p> <p>21 Is that what you said?</p> <p>22 A. It was an inspection finding that said</p> <p>23 the remediation for product complaints, there was --</p> <p>24 there were no observations with product complaints.</p> <p>25 And this was probably in 2008.</p>
Page 231	Page 233
<p>1 no attempt to deliberately omit information.</p> <p>2 I did not put into the report all of the</p> <p>3 verbal communications, such as the -- all of the</p> <p>4 Digitek cases would have arisen only in the U.S.</p> <p>5 Q. Do you --</p> <p>6 A. But I never specifically said I'm not</p> <p>7 going to put this in because it will change the</p> <p>8 opinion in favor of the defendants.</p> <p>9 I never would have done something that</p> <p>10 could have led to that kind of discredibility or lack</p> <p>11 of credibility. There was none of that. And that I</p> <p>12 can give you a definitive answer of no.</p> <p>13 If I forgot to put something in, it was</p> <p>14 an error or I did not realize that I was to put in</p> <p>15 verbal information.</p> <p>16 I did put information in of inspection</p> <p>17 findings of compliance with product complaints. I had</p> <p>18 the interim information for product complaints that</p> <p>19 you showed me for safety.</p> <p>20 But it was actually an inspection</p> <p>21 confirmation, and that's in here. And I put it in</p> <p>22 because I thought this would be one report with some</p> <p>23 -- the conclusions to support. But I did not</p> <p>24 deliberately omit any information.</p> <p>25 Q. Could you tell me -- you just referenced</p>	<p>1 Q. So, then, that would probably be in the</p> <p>2 2008 EIR someplace?</p> <p>3 A. (Witness reviews document.) Yes. Here.</p> <p>4 Q. What page are you on, Doctor? I've got</p> <p>5 a copy here.</p> <p>6 A. 28.</p> <p>7 Q. Thank you.</p> <p>8 And can you direct me to where you are?</p> <p>9 A. Inspection 5, Little Falls, New Jersey,</p> <p>10 18th of September to October.</p> <p>11 And I summarized the only thing I found</p> <p>12 in that was the Establishment Inspection Report, under</p> <p>13 the general discussion, complaints were reviewed,</p> <p>14 there were no deficiencies found.</p> <p>15 I have no ability to assess the impact</p> <p>16 of the sampling of the complaints in this inspection</p> <p>17 and the direct impact on Digitek.</p> <p>18 There was a supplemental document that</p> <p>19 showed -- and there was -- there's a comment from the</p> <p>20 FDA in here, that the compliance with 30-day timeline</p> <p>21 for product complaints improved over the course of</p> <p>22 2007 to the point of the inspection.</p> <p>23 Q. And we have talked before about the fact</p> <p>24 that one thing you would like to see is the product --</p> <p>25 in the course of investigating a product defect, would</p>

59 (Pages 230 to 233)

<p style="text-align: right;">Page 234</p> <p>1 be good communication between the product complaint 2 side and the signal detection side. 3 Do you recall that discussion? 4 A. Yes. 5 Q. And so what you're saying, I think, is 6 that, at least from this observation on Page 28, that 7 as of 2006, the product complaint side appeared to be 8 functioning appropriately; correct? 9 Is that the appropriate -- 10 A. I don't know what the scope of that is. 11 Complaints review. Did they just look at the 12 complaint files? 13 I spent some time trying to assess 14 whether every complaint had an accompanying Health 15 Hazard Assessment. 16 And what I ended up putting weight on 17 was the FDA observation, because they had access to 18 the information in 2008. They were concerned about 19 the lack of ongoing Health Hazard Assessments. 20 And in order to get through all of the, 21 I want to say, lack of evidence and confusion, because 22 I couldn't completely sort that out. 23 And I spoke to them about this, that to 24 base my opinion on the FDA inspector who looked at the 25 primary evidence, even though I did not have the</p>	<p style="text-align: right;">Page 236</p> <p>1 your report, having, you know, engaged in the dialogue 2 with me today, do you feel that you have been misled 3 by the plaintiffs' lawyers regarding the factual basis 4 for your opinions? 5 A. I don't know how to comment on that. I 6 thought that I got a dossier that was not in 7 chronological order. 8 I wasn't sure that I got the full 9 component of the documents. I wasn't sure that the 10 full components had actually been discovered on part 11 of discovery. 12 I cannot say I was deliberately misled, 13 particularly because -- I don't know how to answer 14 that. 15 I had to assume that if they wanted me 16 to write an expert report to be filed in this case 17 that they would take a lot of care to provide the best 18 documentation possible. 19 I can't rule out bias, but I'm -- I have 20 to say that that's not my point to assess. Perhaps I 21 should not have made an assessment about the 22 discovery, but I was surprised by the sampling of the 23 evidence. 24 I thought I would get everything so I'd 25 be able to track things out. That may be my</p>
<p style="text-align: right;">Page 235</p> <p>1 access to it. 2 So that's where I can't come -- I can't 3 reconcile that with the FDA inspector's concern in 4 2008 that there were no accompanying Health Hazard 5 Assessments. 6 I don't know what the overlap was, 7 whether they were fine here and then there were a 8 problem. I can't tell you that. 9 Q. And this is another manifestation of the 10 fact that you were not provided the underlying 11 documents; correct? 12 A. I would assume so, yes. 13 Q. Okay. 14 A. Or I wasn't given any other Health 15 Hazard Assessment other than the one from Dr. Leikin. 16 I had no documentation of any Health Hazard Assessment 17 in 2004. I asked for it. And I looked for them. 18 And I had -- the FDA -- the thing that 19 became the basis of the opinion was that inspector -- 20 FDA inspector in 2008 and their concern with the 21 absence of them. 22 Q. Having heard everything you've heard 23 today in the sense of being shown documents, 24 additional documents today, having gone over all the 25 documents we have in front of us, having gone over</p>	<p style="text-align: right;">Page 237</p> <p>1 misunderstanding on what is adequate evidence. 2 Q. Are you -- 3 A. And my -- is it my inability to render 4 opinion on what is adequate evidence that is the core 5 of the problem? Or do I rely on the people who 6 provide it to me to ensure that this is adequate for 7 the opinion that I render? 8 Q. But you would agree that this is a 9 troubling issue given the lack of information that you 10 had? 11 A. I think it's a -- yeah, I think it's -- 12 I think that -- yes, it does bother me. 13 Q. And at the end of the day, having, 14 again, looked at all the documents, engaged in all the 15 dialogue that we have, are you still willing to 16 continue to serve as an expert witness on behalf of 17 the plaintiffs in this litigation? 18 A. My number one concern in this situation 19 is that I don't do anything considered wrong or I 20 don't have problems with the fact that I'm new to this 21 and I will have to learn certain things. 22 But I don't want to do anything that 23 would be considered incorrect. 24 Now, I agreed to do this. I 25 communicated my concerns. There's an interest for the</p>

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1 plaintiff in my standing by my opinions.
 2 I have little or no interest in going
 3 into a public deposition before a panel of judges and
 4 finding that -- I have to -- I don't -- I don't want
 5 to destroy myself.
 6 I asked if I was -- you know, if I was
 7 considered too lightweight a witness to hold up this
 8 case. I have no way to independently judge that.
 9 But it's extremely important that my
 10 level of expertise is sufficient to hold the weight.
 11 Even if this is an opinion that doesn't support
 12 eventually.
 13 But I have no -- I have no way to
 14 independently judge whether I am truly an expert
 15 witness. What does that constitute?
 16 Is it a few people saying you are, we
 17 want you to do this? We've done it. There may be
 18 another expert witness who's asked to critique your
 19 work.
 20 But I've not been led to believe that,
 21 given my present abilities or knowledge, that pursuing
 22 this is foolish, unethical. I can't say that I've
 23 been led to believe that.
 24 And yet, it's my strength of ego to say
 25 to you, yes, I will stand by this and I will argue and

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1 argue.
 2 And yet, I have doubts about -- I can't
 3 say I've done this five times successfully and,
 4 therefore, I've demonstrated my ability. I can say
 5 that I've been encouraged to pursue this and to submit
 6 this document.
 7 And I've made certain, as I'm doing
 8 this, by asking for external confirmation that I've
 9 not been doing anything foolish or incorrect.
 10 Q. Knowing that there is a lot of money at
 11 stake, knowing that there are court rules in place for
 12 expert reports, knowing that expert reports have to
 13 have appropriate foundations, my question to you is,
 14 are you willing to continue as an expert witness in
 15 this case?
 16 A. The honest answer is, I never wanted to
 17 have to sit expert witness in court. That was not
 18 disclosed to me at the time I agreed to do this. I
 19 agreed to write a report and sit deposition on the
 20 report that I made, on the evidence I was given.
 21 Q. Are you telling me that you weren't told
 22 that you might have to testify in court? Is that what
 23 you're telling me?
 24 A. That was not disclosed to me when I
 25 agreed to do the engagement.

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1 Q. So to the extent -- you've now learned
 2 that; correct?
 3 A. Yes.
 4 Q. Correct?
 5 So to that extent, you were misled;
 6 correct?
 7 A. The --
 8 MR. THOMPSON: Object to the form.
 9 THE WITNESS: The preliminary
 10 communication from the consulting firm is they had
 11 received a request for somebody to do an expert
 12 witness on pharmacovigilance systems.
 13 And I asked what that would entail. And
 14 they said, you'll be sent evidence and you try to come
 15 up with a truthful answer. And you'll have to sit
 16 deposition. But --
 17 BY MR. DEAN:
 18 Q. Excuse me. Mr. Thompson actually gave a
 19 good objection there because -- let me rephrase that
 20 question.
 21 Do you feel you were misled by Smart
 22 Consulting about what your role was going to be in
 23 this litigation?
 24 A. I was led to -- the -- what I agreed to
 25 do would have stopped at the end of today.

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1 I did not agree to sit expert witness
 2 before a panel of federal judges, and then I found out
 3 even later that Pete Miller wanted me to be a witness
 4 in the actual litigation in November.
 5 These things were sequentially disclosed
 6 to me, and my level of comfort with my own
 7 inexperience and not knowing how to gauge my
 8 preparedness was real.
 9 Q. Is it fair to say that you would have
 10 declined this assignment if you had been told at the
 11 beginning that you would have to testify in court
 12 before a jury?
 13 A. I never really wanted to get into this
 14 line of work. I was led to believe this was a very
 15 limited assessment. I was not aware at the outset
 16 that it was a bunch of state litigation that had been
 17 rolled up into a federal case.
 18 There was -- there was no up-front
 19 communication of the extent of the work or the high-
 20 profile nature of the case or -- and I had no
 21 assessment of my potential impact on the outcome.
 22 I don't know whether I'm a small fish or
 23 a big fish in the outcome. I can't say that.
 24 Q. We can agree, though, that you were not
 25 told at the outset that you would have to be a

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Videotaped

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1 testifying witness in court?
 2 You were not told that; correct?
 3 A. No.
 4 Q. You were -- no, you were not told that;
 5 correct?
 6 A. No, that was not disclosed at the
 7 outset. There was sort of a sequential disclosure of
 8 increasing levels of involvement.
 9 Q. When was it that you were finally told
 10 that you would be asked to testify in court before a
 11 jury?
 12 A. I don't know the exact date, but I
 13 believe sort of about the time I had lunch with Pete
 14 Miller. It may have been a phone call, it may be at
 15 the June 2nd lunch.
 16 But -- and I didn't know whether he was
 17 making this assessment to bring me further in the case
 18 based on his preliminary interactions, whether this
 19 was a change in plans, or whether -- or how this all
 20 occurred.
 21 I can't judge -- I really -- I don't
 22 want to judge his motive. I just know there was a
 23 sequential expansion of this.
 24 Q. When you -- I said -- before you
 25 mentioned that I think you were drafting a report on

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1 June 15th.
 2 As you were drafting on June 15th or
 3 thereabouts, at the point where you were writing this
 4 long report, did you understand you were going to have
 5 to testify in court?
 6 A. Possibly, yes. Yes. Yes.
 7 Q. Possibly or for sure?
 8 A. I -- I was told that, in all likelihood,
 9 I would be asked to present at the science day.
 10 Q. At the science day?
 11 A. Which is October.
 12 Q. Were you ever told that you would be --
 13 have you ever been told that you would be asked to
 14 testify in one of the individual actions?
 15 And by that I mean a case in which one
 16 of the plaintiffs is suing the defendants to try to
 17 obtain a money judgment against the defendants.
 18 Have you ever been told that you would
 19 be expected to testify in one of those cases?
 20 A. I was told that they may ask me to
 21 appear in November, in a November case. In all
 22 likelihood, I would be.
 23 And -- oh, no, I do understand
 24 liability. No. I understand the magnitude of this.
 25 I understand what rolling up a bunch of state-level

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1 litigation is. And I understand -- no, I understand
 2 -- I understand what this is.
 3 I just wish I had -- this may be a self-
 4 confidence issue with me. I don't know how to gauge
 5 my preparedness. I may be completely prepared. I may
 6 be very good at this, but I can't tell you whether I
 7 am or I'm not.
 8 Q. But you do wish that it had been
 9 disclosed to you much earlier that you were expected
 10 to testify in front of a court or jury; correct?
 11 A. Yes. I would have preferred my first
 12 expert witness assignment to be limited in scope so
 13 that there was an assurance of the accuracy and the
 14 success.
 15 That the magnitude of this case and that
 16 the questions that I raised about the discovery and
 17 what was being sent to me had not arisen. You know,
 18 maybe I'm out of line as an expert witness saying what
 19 about the discovery?
 20 I assumed that all of these blank
 21 documents, these white spaces, would be sent to me.
 22 When they told me that they weren't sure
 23 they already had them and they may be able to obtain
 24 them, because there may be one more round of
 25 discovery, I just went -- be as -- technically, if I'm

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1 -- I thought I should have everything to track through
 2 the period and maybe track from the consent decree.
 3 But I don't -- I can't tell you I'm
 4 right or wrong based on experience.
 5 Q. Dr. Frank, is it fair to say that you
 6 have significant misgivings about your ability to
 7 qualify as an expert witness and you have significant
 8 misgivings about the quality of the information that
 9 supports the opinion that you have written here?
 10 Would that be fair to say?
 11 A. I hate to say significant misgivings
 12 because I've been assured that -- I've been given
 13 assurance that moving forward with doing this I would
 14 not have embarrassment or problems.
 15 Q. And who has assured you that you would
 16 not have embarrassment in the future as we move
 17 forward in this litigation?
 18 A. The people at Smart Consulting, Nigel
 19 Smart and Denise Smart.
 20 Q. And what did he tell you? Tell me what
 21 assurance -- how did he articulate this assurance that
 22 you would not be embarrassed as we moved forward?
 23 A. Well, he said, really all you have to do
 24 is try to get to truth. We're just seeking that. And
 25 on the evidence presented to you, you try to sort out

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1 what truth is.
 2 And I got to a situation where I was
 3 like, I became concerned that I hadn't been -- I
 4 didn't have all of the communications.
 5 I didn't have -- I didn't have anything
 6 to confirm -- I just got the FDA -- I was asked to
 7 make the determination only on the FDA inspections and
 8 some letters. The letters say we're going to do this.
 9 I don't have the details of what was
 10 done or the tracking that showed that it was done.
 11 And this is stuff that typically is
 12 given to consultants when they go in and assess
 13 vulnerabilities to repeat inspections. And I asked
 14 about it.
 15 Q. So is it fair -- is what you're saying,
 16 there might be a basis for the opinions you've given,
 17 but you're not sure because you haven't seen the
 18 evidence? Is that what you're saying?
 19 Isn't that a fair summary?
 20 A. Yes. I can assure you that I did the
 21 best that I could with what I was given. And I based
 22 it heavily on a few FDA observations from point to
 23 point. But there's interim space where I don't have a
 24 lot of insight into what went on.
 25 It's the FDA inspection, the

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1 communications, and the confirmatory inspections.
 2 MR. DEAN: Thank you.
 3 Give me just a minute, Fred.
 4 VIDEO OPERATOR: Going off the video
 5 record.
 6 The time is 4:23 p.m.
 7 (Discussion off the record.)
 8 VIDEO OPERATOR: We're now back on the
 9 video record.
 10 The time is 4:24 p.m.
 11 MR. DEAN: I do not have any more
 12 questions on behalf of Actavis.
 13 EXAMINATION
 14 BY MR. KAPLAN:
 15 Q. Dr. Frank, I'm Harvey Kaplan.
 16 A. Yes.
 17 Q. I've been listening to your testimony
 18 here today. I want to ask you a few questions.
 19 You've rendered the opinions contained
 20 in your report; right?
 21 A. Yes.
 22 Q. And those are all of your opinions?
 23 A. Yes, they are. I reworded them to say
 24 it is my opinion based on reasonable evidence, and I
 25 did this on June 15th.

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1 And I looked at it, and I said to
 2 myself, I hope that in rewording these statements I
 3 actually have -- am making it on what is considered
 4 reasonable evidence.
 5 That I was provided the reasonable
 6 evidence and I can trust that, and that I was able --
 7 this is -- I was provided huge amounts of documents
 8 about manufacturing and analytical issues.
 9 But there was a question in my mind
 10 about what was reasonable evidence in this case? Do I
 11 have to go through every CAPA tracker?
 12 And I do want to make sure before this
 13 is actually admitted that I don't want to let my
 14 insecurities, which could just be me -- I might have
 15 simply done an analytical analysis.
 16 But, yes, I -- these opinions were
 17 there. I can't see that a lot of things that would
 18 typically have been done have been done.
 19 I was asked -- I was asked to support
 20 certain opinions that counsel wanted supported. And
 21 so what I did was took the evidence and I couldn't see
 22 anything to the contrary.
 23 If I had had a clean inspection in 2008,
 24 I would have said, the evidence for adequate
 25 remediation is the inspection from 2008. Now, he

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1 subdivided the inspection.
 2 Did you see evidence in 2008 that they
 3 did not remediate the quality of the reports? So the
 4 -- there may be overgeneralizations. But they may be
 5 legitimate on -- for certain grounds.
 6 Q. So you were given direction by
 7 plaintiffs' counsel as to certain opinions they wanted
 8 you to express?
 9 A. He said I would like to say that there
 10 were systemic issues that impacted, and I believe it
 11 was the safety signal detection in the Digitek case.
 12 I was actually presented an opinion by counsel.
 13 I wasn't sent the dossiers without -- I
 14 was told the opinion that I was asked to support to
 15 the best that I could. And I did attempt, and you see
 16 there's things that are included here that really sort
 17 out what actually happened.
 18 Q. Plaintiffs' counsel said to you these
 19 are the opinions we want you to express?
 20 A. Yeah. They asked me to go through and
 21 support certain observations.
 22 Q. And you attempted to support those
 23 opinions that you were asked to express by plaintiffs'
 24 counsel; right?
 25 A. Yes.

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<p>1 Q. And you have expressed all of those</p> <p>2 opinions in Exhibit 261; right?</p> <p>3 A. The answer to that is, I cannot tell you</p> <p>4 because I thought these two were going to go together.</p> <p>5 Q. Okay. This is your report, Exhibit 261;</p> <p>6 right?</p> <p>7 A. This was split off. This up until maybe</p> <p>8 it was mid-afternoon, I'd have to look, on the 15th, I</p> <p>9 thought I was submitting all of this together. So</p> <p>10 that there was a much careful tracking between the</p> <p>11 observations and my comments.</p> <p>12 So my concern is that since this was</p> <p>13 split, I never did an independent assessment of a</p> <p>14 hundred percent transfer of every single opinion in</p> <p>15 here to here. There was just sort of a high-level</p> <p>16 overview.</p> <p>17 Q. And what we have been presented is the</p> <p>18 report of Karen A. Frank, M.D., dated June 15, 2010,</p> <p>19 as contained in Exhibit 261, which you have entitled</p> <p>20 Background, Analysis and Conclusions; correct?</p> <p>21 A. Yes. It was segments --</p> <p>22 Q. And Section 3 is called Analysis and</p> <p>23 Conclusions; right?</p> <p>24 A. Yes.</p> <p>25 Q. And your conclusions are all expressed</p>	<p>1 questions about the process of discovery and what was</p> <p>2 presented to me? Have I led you down that path?</p> <p>3 But you are leading me to believe that</p> <p>4 what I have is a sampling of documents that I could be</p> <p>5 asked to determine whether that is reasonable</p> <p>6 evidence, and I may or may not know the real answer to</p> <p>7 that.</p> <p>8 BY MR. KAPLAN:</p> <p>9 Q. Here's the bottom line. You agreed to</p> <p>10 act as an expert witness in this litigation; right?</p> <p>11 A. Yes.</p> <p>12 Q. You're being paid for your services;</p> <p>13 right?</p> <p>14 A. Yes.</p> <p>15 Q. You've been asked to render opinions;</p> <p>16 right?</p> <p>17 A. Yes.</p> <p>18 Q. You have rendered those opinions; right?</p> <p>19 A. Yes.</p> <p>20 Q. And this is our opportunity to test</p> <p>21 those opinions.</p> <p>22 A. Yes.</p> <p>23 Q. To test the basis for those opinions.</p> <p>24 You understand that?</p> <p>25 A. Uh-huh.</p>
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<p>1 in Section 3 of Exhibit 261?</p> <p>2 A. Yes.</p> <p>3 Q. Correct?</p> <p>4 A. Yes.</p> <p>5 Q. Okay. And what I'm wondering as I</p> <p>6 listen to you talk today about evidence that wasn't</p> <p>7 given to you before you prepared this report by</p> <p>8 plaintiffs' counsel, and that you have only learned</p> <p>9 about in the last day, specifically Exhibit 38, the</p> <p>10 FDA's statements on their web site about Facts and</p> <p>11 Myths About Generic Drugs, and other evidence has been</p> <p>12 presented to you today that you have discussed with</p> <p>13 Mr. Dean, what I'm wondering and what I'm concerned</p> <p>14 about is, are you still willing to walk into a court</p> <p>15 of law, raise your right hand and be sworn to tell the</p> <p>16 truth and to stand by with confidence the opinions</p> <p>17 that you have expressed in Exhibit 261?</p> <p>18 MR. THOMPSON: Object to the form.</p> <p>19 THE WITNESS: I'd prefer to have</p> <p>20 substantially more evidence before I had to do that.</p> <p>21 You're leading me to believe through your line of</p> <p>22 questioning that I have formed opinions on what is not</p> <p>23 considered reasonable evidence.</p> <p>24 Now, if I led you to believe that,</p> <p>25 because I'm raising questions, was I remiss in raising</p>	<p>1 Q. You have to say --</p> <p>2 A. Yes.</p> <p>3 Q. And it is our opportunity to determine</p> <p>4 whether or not there is a reasonable, scientific basis</p> <p>5 for the opinions which you have expressed.</p> <p>6 Do you understand that?</p> <p>7 A. Yes.</p> <p>8 Q. And that's what we are doing.</p> <p>9 A. Yes. There is risk in these opinions</p> <p>10 because they were based on there is not evidence</p> <p>11 provided. So there are opinions that are based on the</p> <p>12 absence of the evidence.</p> <p>13 Q. Which is why I asked.</p> <p>14 A. No, I'm not comfortable with that.</p> <p>15 Q. Okay. And that's why I asked you.</p> <p>16 The next step would be to walk into a</p> <p>17 courtroom here in Philadelphia with a federal judge</p> <p>18 heading up the Multi-District Litigation, the judge in</p> <p>19 charge of the Pennsylvania consolidated litigation,</p> <p>20 the judge in charge of the West Virginia litigation,</p> <p>21 the judge in charge of the New Jersey litigation, and</p> <p>22 the judge in charge of the Texas litigation, and for</p> <p>23 you to walk into that courtroom, be called as a</p> <p>24 witness and to get up on the stand and to testify in</p> <p>25 front of that court of law and render these opinions,</p>

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1 and say to these judges under oath that you express
 2 the opinions that are contained in Exhibit 261 to a
 3 reasonable degree of scientific probability that these
 4 are correct and that you, as a medical doctor, who has
 5 worked for various pharmaceutical companies and for
 6 the FDA, can say with confidence that you stand behind
 7 those opinions.
 8 Are you willing to do that?
 9 MR. THOMPSON: Object to the form.
 10 THE WITNESS: Should I discuss this with
 11 you?
 12 MR. KAPLAN: No. Just answer my
 13 question.
 14 MR. THOMPSON: I think that the question
 15 is on the floor.
 16 THE WITNESS: I really don't want to,
 17 but I'm concerned about the fact that it's just that I
 18 only wanted to do the preliminary background work, the
 19 supportive work, and end with a private deposition
 20 like this.
 21 When they told me I had to go to court,
 22 I was like, this is a huge issue. I'm completely
 23 naive with this, and I don't know how to judge my
 24 preparedness.
 25 And I most certainly -- the most

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1 important thing is, I don't want to do anything that
 2 would be considered wrong.
 3 If I've gotten into something where the
 4 work product is inadequate, he's concerned that I'm
 5 backing down based on the presentation of two or three
 6 pieces of evidence. And I'm at a loss to know the
 7 right course of action.
 8 I'd prefer not to testify in a high-
 9 profile case. If I do, I'd like to make certain that
 10 I'm presented everything. I was actually led to
 11 believe that if you presented me with more evidence
 12 today, this would be revised.
 13 And I'm concerned about that, because
 14 that would allow me to go through this if they found
 15 more information and make sure everything was correct.
 16 BY MR. KAPLAN:
 17 Q. This is it. This is our opportunity to
 18 examine you on the report that you have given --
 19 A. I know.
 20 Q. -- in the Multi-District Litigation
 21 that's pending in Charleston, West Virginia, and in
 22 the Pennsylvania consolidated litigation, which is
 23 pending here in Philadelphia.
 24 There are about a thousand cases that
 25 are riding on opinions of expert witnesses here like

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1 yourself.
 2 A. Yeah.
 3 Q. And what I want to know is, whether
 4 you're willing to stand behind these opinions and go
 5 into a court of law and to say with confidence, the
 6 opinions you've given here today, that you stand by
 7 these opinions, as a person of integrity?
 8 A. You have both led me to believe that
 9 there's additional evidence that I was not presented,
 10 even though I asked for it. And proceeding forward, I
 11 could face significant embarrassment, if not
 12 questioning, of the opinions.
 13 And the whole time I did this, I tried
 14 to document very, very carefully. And yet, you're
 15 leading me to believe that this is a great
 16 embarrassment and that I've done an inadequate job and
 17 I can't support what I've done.
 18 He doesn't think I should back down.
 19 And the only thing I can think of is I don't want to
 20 do anything wrong.
 21 Q. What do you think you should do?
 22 A. I would like to -- if I could, I would
 23 like to stop with only doing background supportive
 24 work.
 25 Q. Well, let me say that that's not the

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1 option right now.
 2 A. It's one or the other?
 3 Q. Yes. Either you go forward or you back
 4 down.
 5 A. What if I choose not to go forward?
 6 What are the implications?
 7 Q. That's up to you. You can say, I
 8 withdraw as an expert here. I'm not comfortable with
 9 it.
 10 A. But what are the implications of that?
 11 Will I be in a lot of trouble?
 12 Q. You won't be in trouble. You just won't
 13 be an expert in this litigation.
 14 MR. THOMPSON: Well, I am going to
 15 object and I am going to say that this would be
 16 something that I would view as something that would --
 17 I would be entitled to confer with the expert witness
 18 about is that question about withdrawal.
 19 THE WITNESS: Okay.
 20 MR. THOMPSON: Certainly you can
 21 question her about the report. You can question her
 22 about the documents. You can question her about all
 23 that.
 24 But I believe that I would have an
 25 opportunity to confer with her about that issue of

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1 whether she would continue employment or not.

2 BY MR. KAPLAN:

3 Q. What do you want to do?

4 A. The right thing.

5 Q. What do you think that is?

6 A. The safe thing is to withdraw. If at
7 this point I can withdraw and there will be no
8 questions that I've done the best I could and there's
9 tremendous -- there may be more risk to everyone if I
10 proceed.

11 You're basically saying that if at this
12 point there's question that putting me on a witness
13 stand can be an embarrassment or jeopardize the
14 litigation, then the right thing to do would be to
15 withdraw.

16 But I hope I could do that without being
17 accused of doing anything wrong. I would hope that
18 people would say she did the best she could with what
19 she was given and under the guidance she was given.

20 But I have been so frightened -- when I
21 say frightened, since I started this, that I would do
22 something wrong and there would be consequences, that
23 this could just be my fear because I'm naive to this.

24 I've stayed away from it even though
25 people have encouraged me to get into it.

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1 And I just -- I don't want to do
2 anything wrong where there would be consequences for
3 me, even to question my credibility. That's my number
4 one concern.

5 And I may have to say that I did
6 something -- I was told -- I keep being told to have
7 self-confidence. But right now, I don't. There's
8 significant concern.

9 And, of course, you would want me to not
10 be a witness for the plaintiff. I guess the fewer
11 there are, I just don't want to do anything wrong.
12 And I'm actually scared to move forward.

13 I can probably put this together and
14 pick through all of the statements.

15 I was able to answer Mr. Dean when he
16 asked me about the 2007 letter and say, well,
17 corrective actions imply there was something wrong
18 that had to be corrected. I can make the analysis.

19 But you're leaving open to me a question
20 of the wisdom of it and of subjecting my client to
21 unnecessary risk in a court of law because I'm not
22 necessarily strong enough to stand up to it when they
23 feel that I am and a few other people do.

24 So I'm willing to say, well, I've done
25 something, I have learned.

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1 But at this point, I didn't know that
2 this was such a heavy assignment when I agreed to do
3 it, and I didn't feel that I should withdraw when they
4 told me this when they felt I was strong enough.

5 But now I'm being seriously questioned,
6 and I would have preferred to have this be a limited
7 assignment and to not jump right into a very big case.

8 As you said, there's very, very high
9 risks. There's no way I can assess the real risk.
10 And all that I can think in my head right now is I
11 just don't want to do the wrong thing.

12 And that's what I did for two to three
13 weeks when I took this assignment.

14 I just don't want to get into anything
15 that's wrong, that I can't do appropriately. That's
16 my only concern.

17 Q. Well, my concern and Mr. Dean's concern
18 is that our clients are being accused of wrongdoing.

19 A. I'm not trying to do that.

20 Q. And our clients are being accused of
21 selling and distributing --

22 A. Oh, your clients. Oh, I'm sorry.

23 Q. -- defectively manufactured Digitek.

24 A. I was thinking the law firm. I trusted
25 their counsel. I thought you were asking me -- no, I

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1 take that initial response back.

2 Q. I want you to understand this is very
3 serious business.

4 A. It's very serious.

5 Q. Millions of dollars are being sought
6 from our clients.

7 Do you understand that?

8 A. Absolutely.

9 Q. And --

10 A. I'm not that naive. I'm not --

11 Q. Plaintiffs are offering expert
12 testimony, like your testimony, to support their case.

13 Do you understand that?

14 A. Yes. I do understand. I know what this
15 means. I know what's at stake.

16 Q. To support their allegations of
17 wrongdoing against our clients.

18 You understand that?

19 A. Yes.

20 Q. And that's what you're doing in this
21 case.

22 A. He asked me earlier whether I was a
23 witness for the plaintiff or a truth seeker. And what
24 happened when I started asking for more information
25 was, I'm -- I became more of a truth seeker.

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Videotaped

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1 I told you this. I don't know how much
2 this all supports directly the Digitek case.
3 I never saw information that subset the
4 direct impact on Digitek. I can only make
5 generalization statements. And I hope they aren't
6 wrong generalizations. There is more evidence to be
7 obtained.
8 Q. And you certainly never saw any evidence
9 that any person received defectively manufactured
10 Digitek, did you?
11 A. No.
12 MR. THOMPSON: Objection. Asked and
13 answered.
14 BY MR. KAPLAN:
15 Q. Did you?
16 A. Well, I was told this would be asked.
17 Now, what I know is that there were an influx of cases
18 after the recall was announced. I have not been given
19 any of that evidence. That was sent to someone else.
20 Q. So what I'm saying to you is --
21 A. I haven't.
22 Q. -- you've never seen any evidence --
23 A. No.
24 Q. -- to support an allegation that any
25 consumer ever ingested defectively manufactured

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1 Digitek, have you?
2 A. No, I've not been provided that. I've
3 been provided evidence -- evidence that says that it's
4 worth being investigated further. But I've not really
5 been able to investigate it further.
6 Q. And you're a person who worked for and
7 was trained by the FDA?
8 A. Yes.
9 Q. You had good training at the FDA?
10 A. I thought it was very, very good.
11 Q. Quality, competent people?
12 A. Yes.
13 Q. You have faith and confidence in the
14 FDA?
15 A. Yes. I'm -- I'm -- I do understand all
16 of the issues with other litigation. It's not my
17 point to comment here.
18 This issue of how far I was to comment
19 on this assessment has come up. I was told that
20 leaving this comment in about the headquarters
21 oversight was okay.
22 Q. Just follow me. Follow me here for a
23 little bit.
24 And being a person who worked for the
25 FDA, who was trained by qualified and competent people

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1 at the FDA, and who places great reliance on the
2 integrity of the FDA --
3 A. Yes.
4 Q. -- you do that, don't you?
5 A. Yes.
6 Q. And you have testified that in the
7 opinions you've rendered, you relied upon FDA
8 inspection reports --
9 A. Yes.
10 Q. -- and what the FDA inspectors have
11 said?
12 A. Yes. Solely. I am relying on their
13 assessment of the primary data.
14 Q. And so, after all is said and done,
15 after all of these inspections and after all of your
16 reliance on what the FDA inspectors have said with
17 regard to the primary data and after the recall, we
18 come full circle, do we not, to Plaintiffs' Exhibit
19 38, which you were shown today?
20 A. Yeah.
21 Q. Right?
22 A. Uh-huh. Yes.
23 Q. Okay. And that's entitled Facts and
24 Myths About Generic Drugs; right?
25 A. Yes.

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1 Q. And that's a statement of the FDA;
2 right? Correct?
3 A. Yes.
4 Q. And it's a very important statement of
5 the FDA, isn't it?
6 A. Yes.
7 Q. It speaks directly to the Digitek
8 recall, doesn't it?
9 A. Yes.
10 Q. And it is a statement to the public
11 about the Digitek recall; right?
12 A. Yes.
13 Q. The myth, as expressed by the FDA on
14 Page 2, is that there are quality problems with
15 generic drug manufacturing. They characterize that as
16 a myth; right?
17 A. Yes.
18 Q. And they further say, as to the myth, A
19 recent recall of generic Digoxin (called Digitek)
20 shows that generic drugs put patients at risk.
21 The FDA says that's a myth; correct?
22 A. Yes.
23 Q. And under Facts, the FDA says, In our
24 best judgment, given the very small number of
25 defective tablets that may have reached the market and

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<p style="text-align: right;">Page 266</p> <p>1 the lack of reported adverse events before the recall, 2 harm to patients was very unlikely. 3 That's what the FDA says is a fact; 4 correct? 5 MR. THOMPSON: Object to the form. 6 THE WITNESS: That was my concern when I 7 started asking questions of is there any information 8 that I can have that would tell me how -- what is the 9 percentage of any given batch affected, and what is 10 the chances that multiple pills ended up in one 11 bottle? 12 BY MR. KAPLAN: 13 Q. And now you have seen the FDA's 14 statement as to this Digitek recall, haven't you? 15 A. Yes. 16 Q. And the FDA continues to stand by that 17 statement, don't they? 18 A. Yes. 19 Q. They haven't changed it since the 20 recall, have they? 21 A. No, not -- not on June 15th. 22 Q. And so we come full circle; correct? 23 A. Well, at this point, I have no 24 information on Digitek, per se, of any safety signal 25 detection. I can't tell you, and I have -- I raised</p>	<p style="text-align: right;">Page 268</p> <p>1 Q. -- as to Facts and Myths About Generic 2 Drugs, and their specific statements about Digitek, 3 were never revealed to you by plaintiffs' lawyers, 4 were they? 5 A. No. And I will say -- 6 Q. Were they? 7 A. No. I did confirm when I took this case 8 that all that I was required to do is to seek to come 9 to truth. And that's all that I had to do. 10 Q. And do you believe that the FDA's 11 statement in Exhibit 38, statements that I just read 12 to you, are the truth? 13 A. Yes. 14 MR. KAPLAN: Thank you very much. 15 MR. THOMPSON: I'm going to have some 16 questions. I understand Mr. Moriarty objects to my 17 asking questions, or at least he did the other day. 18 MR. KAPLAN: Well, Mr. Moriarty isn't 19 here. 20 MR. THOMPSON: Well, I'm going to ask a 21 few questions. 22 EXAMINATION 23 BY MR. THOMPSON: 24 Q. Doctor, let me ask you to look at 25 Defendant's 38.</p>
<p style="text-align: right;">Page 267</p> <p>1 this, and that's actually in my comments. 2 The issues with the pharmacovigilance 3 system are broad. There was an absence of signal 4 detection during the 2004 to 2006. 5 If the FDA looked into that and there is 6 nothing else that would refute this statement, I will 7 never be able to refute it even if given the evidence. 8 And if you say that the FDA has already 9 done that, and said that, then, you know, I can sit 10 here with the evidence. I will just be confirming 11 this. 12 Q. This is the FDA's bottom line statement 13 as to Digitek, isn't it? 14 MR. THOMPSON: Object to the form. 15 THE WITNESS: Yes. 16 BY MR. KAPLAN: 17 Q. You believe the FDA, don't you? 18 A. Yes. 19 Q. And this is the information -- this is 20 part of the information that was never disclosed to 21 you by plaintiffs' lawyers, isn't it? 22 A. And I did not seek it independently. 23 Q. This information, Exhibit 38, the FDA's 24 statement -- 25 A. No.</p>	<p style="text-align: right;">Page 269</p> <p>1 Do you have that in front of you? 2 A. Yes. 3 Q. You have been asked and your attention 4 has been directed to one sentence in paragraph four of 5 five bullet items. 6 Do you see that? 7 A. This right there (indicating)? 8 Q. Yes. 9 A. Okay. 10 Q. Do you see that each time you've been 11 asked about this document, your attention has been 12 directed to the second sentence of bullet line item 13 number four? 14 A. Yes. 15 Q. Let's go back up and ask you to read the 16 entire bullet item of number three, bullet item number 17 three. 18 A. Although Actavis attempted to remove the 19 affected Digitek tablets through visual inspection, 20 FDA determined that this method of removal was 21 inadequate to assess the product's quality and 22 consistency, in accordance with GMP regulations, good 23 manufacturing -- current good manufacturing practice, 24 parenthesis, CGMP regulations. 25 Q. Now, read the entire bullet point number</p>

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Karen A. Frank, M.D.

Videotaped

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<p>1 four for me.</p> <p>2 A. Since the detection of the manufacturing</p> <p>3 problem, FDA has been actively engaged with this</p> <p>4 company to ensure that all potentially infected lots</p> <p>5 have been recalled.</p> <p>6 In our best judgment, given the very</p> <p>7 small number of defective tablets that may have</p> <p>8 reached the market and the lack of reported adverse</p> <p>9 events before the recall, harm to the patients was</p> <p>10 very likely (sic).</p> <p>11 Q. Now, do you believe that the FDA's</p> <p>12 judgment with regard to its determination of violation</p> <p>13 of good manufacturing practice would be as</p> <p>14 authoritative as that that you just answered</p> <p>15 Mr. Kaplan?</p> <p>16 MR. DEAN: Objection to form, and also</p> <p>17 lack of expertise on inspection procedures, which</p> <p>18 she's already testified to.</p> <p>19 MR. KAPLAN: I join that objection.</p> <p>20 THE WITNESS: No. I had no way to come</p> <p>21 up with this conclusion that the FDA came up with</p> <p>22 because I had no information.</p> <p>23 It was redacted out of the documents and</p> <p>24 I wasn't provided access to any information on</p> <p>25 analysis of the batches. I still think a lot was</p>	<p>1 about how to quantitate abnormal pills and lots, I</p> <p>2 can't tell you what procedure they should use.</p> <p>3 Q. Doctor, let me ask you a couple</p> <p>4 questions.</p> <p>5 Do you know what period of Digitek drugs</p> <p>6 were recalled, for what time period?</p> <p>7 A. It started June 6th, 2006, and I believe</p> <p>8 went for two years, up until the May -- or the April</p> <p>9 -- the date of the release of the recall. But I did</p> <p>10 look at that.</p> <p>11 And I tried to sort it out because it</p> <p>12 had to do with -- it wasn't manufacture date, it was</p> <p>13 market release date.</p> <p>14 Q. All right.</p> <p>15 A. And I did take time to sort that out and</p> <p>16 then I was sort of out of scope.</p> <p>17 Q. All right. Well, let me ask this: When</p> <p>18 this FDA facts and myths document was posted, was</p> <p>19 Digitek being made available to consumers in the</p> <p>20 United States?</p> <p>21 A. When this was posted, I don't know what</p> <p>22 date it was posted. And I don't know whether Digitek</p> <p>23 was still in the market. I can't answer that. I was</p> <p>24 unable to find the date when he asked me for it.</p> <p>25 Q. Well, if, assuming that the bullet point</p>
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<p>1 incinerated.</p> <p>2 And there was no data mining of the</p> <p>3 database. We're assuming that when the FDA read this,</p> <p>4 that they were satisfied with the case reporting.</p> <p>5 They did not go back and re-data mine that database.</p> <p>6 BY MR. THOMPSON:</p> <p>7 Q. Did you --</p> <p>8 A. But I don't know. I have an absence of</p> <p>9 information.</p> <p>10 And it's affecting -- it's clearly</p> <p>11 affecting my security at standing here and saying yes</p> <p>12 or no, because what I've been asked to render is very</p> <p>13 generalized, and I would prefer to have access to the</p> <p>14 remainder of that information.</p> <p>15 Q. All right.</p> <p>16 A. If, indeed, this is the bottom line,</p> <p>17 then I'm concerned that even if I asked for all the</p> <p>18 information, I won't come up with a different answer.</p> <p>19 If this above there says, well, nobody</p> <p>20 ever looked at the lots before they ended up on the</p> <p>21 market and, therefore, this unlikely is based on,</p> <p>22 well, we never looked at the lots, that's what he's</p> <p>23 implying, that there is some uncertainty to that.</p> <p>24 And now the question is, can I actually</p> <p>25 say -- because I'm not a GMP expert and I know nothing</p>	<p>1 says lack of reported adverse events before the</p> <p>2 recall, can you date this as to when it was vis-a-vis</p> <p>3 the recall?</p> <p>4 A. The recall package was dated April 25th,</p> <p>5 2008. So it was up until that point. It was -- it</p> <p>6 was -- the press release was the 25th of April.</p> <p>7 So you can say that up until public</p> <p>8 awareness of the recall on the 25th that there was no</p> <p>9 impact of the recall on the reporting rates.</p> <p>10 So that the reporting rates up until the</p> <p>11 recall were not induced reporting rates. That as soon</p> <p>12 as that press release went out, the increase in</p> <p>13 reporting rates was significantly influenced by the</p> <p>14 knowledge of the recall.</p> <p>15 And I cannot comment because I haven't</p> <p>16 looked at the cases. This is someone else.</p> <p>17 Q. All right.</p> <p>18 A. How many of those were potentially</p> <p>19 frivolous cases and how much were concerning -- how</p> <p>20 many cases do we have of documented supratherapeutic</p> <p>21 digitalis levels, how many cases took the tablet.</p> <p>22 I do know that you can see digitalis</p> <p>23 toxicity at therapeutic doses. You don't have to be</p> <p>24 supratherapeutic to have the toxicity.</p> <p>25 So it makes it very, very difficult to</p>

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1 sort out based on clinical symptoms whether you're
2 dealing with suprathreshold digitalis.
3 And I was very thankful that I did not
4 have to render an expert opinion on that, that you
5 probably took doctors who were experts in digitalis.
6 Q. All right. That actually raises a
7 question.
8 Is an adverse event report, is that
9 voluntary or mandatory at the clinician's level?
10 A. In the U.S., it's voluntary.
11 Q. If a practicing physician had a patient
12 who showed symptoms of Digoxin toxicity, would that,
13 as a common practice, generate an adverse event
14 report?
15 MR. KAPLAN: Objection. Calls for
16 hearsay.
17 THE WITNESS: Well, that's difficult to
18 say.
19 With a drug that's as old as Digoxin and
20 as established, I can tell you right now that there
21 are hospital admissions for digitalis toxicity. That
22 when I was a resident I was not aware of MedWatch.
23 BY MR. THOMPSON:
24 Q. All right.
25 A. The issue when you're in a drug company

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1 is that a post-marketing report in most companies
2 defaults to possible.
3 By virtue of the fact that the person
4 had a clinical suspicion, when it's reported to the
5 company, when you do that relatedness assessment
6 inside the company, many big pharma SOPs default to
7 possible by virtue of the fact that the person who is
8 not subject to mandatory reporting reported the case.
9 So they default to submission to the
10 FDA. There is some variability, but my understanding
11 is the industry standard for post-marketing, when it's
12 unsolicited, defaults to possible.
13 Q. All right. Let me ask you to look at
14 Defendant's Number 20. I think it's on your -- it
15 should be on your stack there.
16 No? It should be --
17 MR. DEAN: This is a stack here, I was
18 trying to get it organized. Let me find it for her.
19 Here you go.
20 BY MR. THOMPSON:
21 Q. All right. You were shown -- I'm going
22 to hand you Defendant's 20. You were shown this
23 summary of findings of the CGMP inspection.
24 Do you recall?
25 A. Yes.

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1 Q. You recall -- I think your testimony was
2 you had not seen this before?
3 A. No.
4 Q. Okay. Now, what's the date of the CGMP
5 inspection?
6 A. December 1st, 2004.
7 Q. All right. Is there any date, is there
8 any operative date, that's been involved in any
9 question that you've been asked that includes
10 12/1/2004?
11 A. No. However, the investigation report
12 for the double-thick Digitek tablet was July 2004.
13 Q. All right.
14 A. I'm not sure what date. But it was five
15 to six months before this repeat inspection.
16 Q. All right. And do you know the date of
17 production of this document to the plaintiffs in this
18 case?
19 A. No. I do not know whether this was
20 inadvertently omitted from my packet, whether it was
21 in the millions of pages, some -- and not sent to me
22 or whether it was sent to the plaintiffs late, and,
23 therefore, we have evidence after I was submitted my
24 dossiers --
25 Q. All right.

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1 A. -- that I should be allowed to consider
2 as later evidence.
3 Again, this is -- I keep saying my
4 naivete and maybe it's just my foolishness to say my
5 naivete. But there may be issues with this. There
6 may be late discovery that I would be permitted to
7 review without any embarrassment.
8 Q. All right. Now, let me ask you to pull
9 out the big -- the attachment to your report.
10 MR. DEAN: Excuse me.
11 If we're done with that, let me get that
12 one back in the stack of exhibits so it doesn't get
13 misplaced.
14 MR. THOMPSON: Thank you.
15 THE WITNESS: I did ask --
16 BY MR. THOMPSON:
17 Q. The big appendix. The big appendix.
18 A. Yes. I did ask if there was going to be
19 more discovery, if discovery was complete, if all of
20 these documents had been obtained, and if I could
21 request these missing documents in discovery, and they
22 said there may be that chance.
23 Q. All right.
24 A. And I was led to believe that it was
25 permissible to proceed in such a manner, that as a

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1 witness, I was allowed to question this and ask for
2 more information.
3 And that if I was provided it, that I
4 could modify my report based on the submission of new
5 evidence to me.
6 That filing that report would not
7 embarrass me, the Miller form, or Motley Rice, if
8 another round of discovery would produce new evidence.
9 Q. Okay. Let's go to Page 20 and 21 of
10 that attachment.
11 A. Okay.
12 Q. Now, there in the middle of the page of
13 Page 20 there is a lengthy quotation.
14 A. Yes.
15 Q. You see that? What is that quotation
16 from?
17 A. It's from Reference 4 on Page 2. And
18 Reference 4 is the August 15th warning letter based on
19 the company response of February 28th.
20 Q. And what day is that?
21 MR. DEAN: What year?
22 MR. THOMPSON: Yes.
23 BY MR. THOMPSON:
24 Q. What's the date?
25 A. August 15th, 2006 warning letter based

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1 on the company response dated February 28th, 2006.
2 So what happened with the 2006
3 inspection is the company sent a response on February
4 28th to the 483, and then again on February 28th. And
5 the FDA sent a revised warning letter and had
6 concerns.
7 Q. All right.
8 A. Yes.
9 Q. Now, let's go to Page 21.
10 A. Okay.
11 Q. And you have a comment on the following
12 page --
13 A. All right.
14 Q. -- where you relate the -- and maybe I
15 should just get you to read it. If we go down one,
16 two -- the sentence that begins In light of.
17 Do you see that?
18 A. Yes. Should I read the entire
19 paragraph?
20 Q. Just read out loud the sentence that
21 begins with In light of.
22 A. In light of the FDA 483 inspection
23 observations from May 20th, 2008, it is my opinion
24 based on reasonable degree of evidence that the
25 compliance remediation in 2006 was not adequate either

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1 in content or in implementation to remediate the
2 inspection findings of delinquent expedited reporting,
3 inadequate case follow-up, or the quality of reports.
4 Q. Okay. Now, if I hand you Defendant's
5 Exhibit 87, which you saw for the first time today
6 during the -- and I'll just hand you my copy of it,
7 which you saw for the first time today, and you
8 indicated that was one of the three documents that
9 caused you to worry about your -- the quality of your
10 opinions.
11 Do you see that?
12 A. Yes.
13 Q. And you agree that that's the letter
14 that caused you to question that; is that right?
15 A. Yes.
16 Q. Okay. Read me the two sentences back to
17 back.
18 Well, read me the entire second
19 paragraph.
20 A. New Jersey District has reviewed your
21 response regarding the Adverse Drug Experience
22 reporting deficiencies. Your corrective actions and
23 the revised procedures appear to be satisfactory.
24 We will, however, confirm the adequacy
25 of your corrective actions and assess the overall ADE

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1 reporting system during a future inspection.
2 Q. Okay. Now, what do you think the last
3 sentence of that paragraph means?
4 A. They will confirm the implementation,
5 the adequacy of the implementation. At this point it
6 appears they're okay with the content.
7 They will confirm the adequacy of the
8 implementation and they will expand the confirmation,
9 not just to the adequacy of the directed corrective
10 actions to the observations in 2006 --
11 Q. Okay.
12 A. -- but they will expand this to include
13 the adequacy of the entire ADE system.
14 Q. All right. Now --
15 A. This --
16 Q. Let me ask you a question.
17 A. Okay.
18 Q. I want to go back to your comment at
19 Page 21. Okay.
20 Now, do you stand by your opinion that
21 was expressed on Page 21 that taking the findings of
22 the 2006 inspection and taking the findings of the
23 2008 inspection that the compliance remediation was
24 not adequate either in content or implementation to
25 remediate the inspection findings?

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Karen A. Frank, M.D.

Videotaped

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<p>1 MR. DEAN: Objection.</p> <p>2 MR. KAPLAN: I'm going to object and ask</p> <p>3 for some clarification. I was told, I thought it was</p> <p>4 her sworn testimony, that Exhibit 261, that all of her</p> <p>5 opinions were contained in Section 3 entitled Analysis</p> <p>6 and Conclusions of Exhibit 261?</p> <p>7 THE WITNESS: But I also stated that</p> <p>8 this document was split in a very short time frame and</p> <p>9 there was a chance that not all of them were</p> <p>10 completely transferred. I believe this is in 261.</p> <p>11 MR. KAPLAN: Well, I'd like to have the</p> <p>12 reference to it because I'm trying to -- what I was</p> <p>13 trying to do is figure out what are your opinions.</p> <p>14 And I looked in the analysis section,</p> <p>15 and I'll just tell you that I looked for words such as</p> <p>16 it is my opinion that or it is my opinion based on the</p> <p>17 evidence that.</p> <p>18 And I counted, starting on Page 5, going</p> <p>19 through Page 9, seven -- seven opinions that you</p> <p>20 expressed in there. And so I did the best I could.</p> <p>21 Following that, I asked you the question</p> <p>22 are all your opinions contained in 261. Your answer</p> <p>23 was, yes, you relied upon that.</p> <p>24 So I just don't understand what it is</p> <p>25 we're being asked to do here to try to suck out</p>	<p>1 entirety, provide evidence that the pharmacovigilance</p> <p>2 system and the accompanying quality systems remain</p> <p>3 inadequate to ensure compliance with regulatory</p> <p>4 reporting or requirements of the compliance</p> <p>5 remediation, either from the MHRA inspection of 2005</p> <p>6 or the FDA inspections in the first quarter of 2006.</p> <p>7 I did not go into the specifics of the</p> <p>8 single-case reporting or the narrative quality. I</p> <p>9 would have to go back and verify that.</p> <p>10 But the -- when this really became a</p> <p>11 pressured situation to make a determination, I relied</p> <p>12 very, very heavily on this 2008 inspection to show</p> <p>13 that there were persistent observations that were not</p> <p>14 remediated.</p> <p>15 I couldn't say whether it was the</p> <p>16 content of the plan because I wasn't provided that, or</p> <p>17 the implementation. Because it could be a bad plan</p> <p>18 with good implementation or it could be a good plan</p> <p>19 with bad implementation.</p> <p>20 MR. KAPLAN: If there were remediation</p> <p>21 problems, do you think the FDA would have said in</p> <p>22 Exhibit 38 that there was a very -- it's very unlikely</p> <p>23 that anybody was harmed as the result of defective</p> <p>24 Digitek?</p> <p>25 MR. THOMPSON: Let me interrupt. It</p>
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<p>1 opinions from another document that in your opinion --</p> <p>2 MR. THOMPSON: This entire document was</p> <p>3 produced timely. It's been in your possession. I'm</p> <p>4 sure you've had people analyzing it. And the words</p> <p>5 have been in your possession for --</p> <p>6 MR. KAPLAN: So you're telling me that</p> <p>7 not all of her opinions are in Exhibit 261 --</p> <p>8 THE WITNESS: I modified this.</p> <p>9 MR. KAPLAN: -- the June 15, 2010</p> <p>10 document prepared by Dr. Karen A. Frank, entitled</p> <p>11 Background, Analysis and Conclusions, that's not all</p> <p>12 of her opinions?</p> <p>13 We have to go searching beyond that; is</p> <p>14 that right?</p> <p>15 MR. THOMPSON: I don't know that you</p> <p>16 have to search. All you have to do is read it.</p> <p>17 MR. KAPLAN: Well, I've read this and</p> <p>18 I've tried to sort out her opinions, and whenever she</p> <p>19 expresses an opinion she says it is my opinion that</p> <p>20 and I've relied upon that.</p> <p>21 And that's where I get seven opinions,</p> <p>22 so I don't understand where else. This is not a game.</p> <p>23 THE WITNESS: I have this -- I have this</p> <p>24 on Page 5, paragraph three, the last sentence.</p> <p>25 These observations, taken in their</p>	<p>1 sounds as though we're going to go a little more than</p> <p>2 five minutes and he -- I think we're running out of</p> <p>3 tape.</p> <p>4 VIDEO OPERATOR: We have one left.</p> <p>5 MR. KAPLAN: Will you answer that</p> <p>6 question?</p> <p>7 MR. THOMPSON: Have I passed the chair</p> <p>8 to you?</p> <p>9 No, wait. Go ahead. Go ahead. Go</p> <p>10 ahead.</p> <p>11 MR. KAPLAN: Okay.</p> <p>12 MR. THOMPSON: Go ahead.</p> <p>13 MR. DEAN: First, we need to change the</p> <p>14 tape.</p> <p>15 VIDEO OPERATOR: Going off the</p> <p>16 videotape.</p> <p>17 This is the end of Tape 5.</p> <p>18 The time is 5:11 p.m.</p> <p>19 (Discussion off the record.)</p> <p>20 (The court reporter read back the</p> <p>21 following:</p> <p>22 "QUESTION: If there were remediation</p> <p>23 problems, do you think the FDA would have said in</p> <p>24 Exhibit 38 that there was a very -- it's very unlikely</p> <p>25 that anybody was harmed as the result of defective</p>

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<p>1 Digitek?")</p> <p>2 VIDEO OPERATOR: We're now back on the</p> <p>3 videotape.</p> <p>4 This is the start of Tape 6.</p> <p>5 The time is 5:15 p.m.</p> <p>6 THE WITNESS: Okay. I do not know what</p> <p>7 evidence the FDA considered in reaching the opinion</p> <p>8 that there was no risk to public health, whether that</p> <p>9 was only based on the evidence in the AERS database</p> <p>10 and the probability of this being a high-frequency</p> <p>11 event with pills on the market.</p> <p>12 There was enough concern to draw the</p> <p>13 pills from the market. I have no idea whether it was</p> <p>14 one pill, a hundred. There is no, at this point. But</p> <p>15 you have to rely that there was some sort of an FDA</p> <p>16 analysis.</p> <p>17 Whether or not it includes the</p> <p>18 remediation plan or an assessment of the system that</p> <p>19 produced the data, I don't know the answer to that.</p> <p>20 If --</p> <p>21 EXAMINATION</p> <p>22 BY MR. KAPLAN:</p> <p>23 Q. You have a high degree of confidence in</p> <p>24 the FDA?</p> <p>25 A. Yes. If --</p>	<p>1 It includes this Establishment Inspection Report.</p> <p>2 So the Establishment Inspection Report</p> <p>3 that I base my opinion on was available to them at the</p> <p>4 time they rendered that opinion and they are</p> <p>5 differing. They are saying it doesn't impact Digitek.</p> <p>6 I am making a generalization of saying</p> <p>7 these defective systems may have impacted signal</p> <p>8 detection because there's a lot of evidence that these</p> <p>9 things weren't done.</p> <p>10 The FDA inspectors are concerned with</p> <p>11 Health Hazard Assessments that aren't done in</p> <p>12 realtime.</p> <p>13 There's concern that there's still lack</p> <p>14 of single-case reporting, which means the FDA may or</p> <p>15 may not have seen them all. They're saying at this</p> <p>16 point, based on what they know, this is okay.</p> <p>17 You're presenting me with evidence that</p> <p>18 may, indeed, negate my opinion.</p> <p>19 And I'm starting to feel more</p> <p>20 comfortable now with the process of being a witness in</p> <p>21 deposition that I am to modify my position truthfully</p> <p>22 based on new evidence, that this is what I've been</p> <p>23 hired to do.</p> <p>24 If I had had all of this, my opinions</p> <p>25 would probably have been more specific, definitely</p>
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<p>1 Q. And you don't believe that the FDA would</p> <p>2 make such a statement lightly, do you?</p> <p>3 A. My opinion is that they felt these</p> <p>4 remediation processes were so serious that there could</p> <p>5 be a bunch of cases in the Actavis database</p> <p>6 unreported, they would have gone in and looked.</p> <p>7 They would have pulled up the coded</p> <p>8 cases and text search.</p> <p>9 Because my understanding, based upon</p> <p>10 only on verbal communications, the kind of, you know,</p> <p>11 afternoon coffee conversations, is that those are the</p> <p>12 kind of things they do when they have a market</p> <p>13 withdrawal.</p> <p>14 But I do not know if that is standard in</p> <p>15 a recall of generic drugs.</p> <p>16 I can't comment on the adequacy of their</p> <p>17 response. And I don't know whether it was done or</p> <p>18 not.</p> <p>19 Q. All right.</p> <p>20 A. But the idea that they issued a release</p> <p>21 and they left it out on the web site unmodified means</p> <p>22 at this point they don't believe there's a risk.</p> <p>23 That's their position.</p> <p>24 The FDA is maintaining their position</p> <p>25 based upon present data. I do not know what that is.</p>	<p>1 more defensible on deposition. But they would not</p> <p>2 have been subject to this new information.</p> <p>3 And I'm trying to couch my response to</p> <p>4 you to give diligence to all parties in the attempt to</p> <p>5 handle this situation in realtime with the deadline</p> <p>6 correctly. I don't want to be seen as accusing the</p> <p>7 Miller firm or Motley Rice.</p> <p>8 I think there was issues with how the</p> <p>9 data was gathered in discovery and maybe disseminated.</p> <p>10 There may be the opinion that the</p> <p>11 discovery was completely adequate on this case or my</p> <p>12 request for further information may have been</p> <p>13 honored. But I was told to try to come to truth based</p> <p>14 on the evidence that I was provided.</p> <p>15 So the evidence that you've provided to</p> <p>16 me is that the FDA may have completely overruled my</p> <p>17 opinion, and that based on their knowledge of</p> <p>18 compliance and the adequacy of the single-case reports</p> <p>19 that still led me to say there could be vulnerability,</p> <p>20 these are defective processes, the FDA was willing to</p> <p>21 admit that statement.</p> <p>22 And the strength of the FDA and their</p> <p>23 access to information I don't have can completely</p> <p>24 negate my opinion based on these -- this subset of</p> <p>25 evidence.</p>

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<p>1 MR. KAPLAN: Thank you.</p> <p>2 MR. THOMPSON: I don't have anything</p> <p>3 else.</p> <p>4 MR. KAPLAN: I appreciate your candor.</p> <p>5 I appreciate you --</p> <p>6 THE WITNESS: I was asked how to handle</p> <p>7 this. I was told to try to seek truth.</p> <p>8 MR. KAPLAN: And that's what we're</p> <p>9 trying to seek here.</p> <p>10 THE WITNESS: And I just -- I want to be</p> <p>11 certain the fact that I still don't have all the</p> <p>12 information, that what the FDA had really is</p> <p>13 sufficient to overturn mine. That's the question at</p> <p>14 hand here.</p> <p>15 And if there is any other question of</p> <p>16 the adequacy of that -- of the information on the FDA</p> <p>17 statement, if they -- if they did not have sort of</p> <p>18 this linear timeline that I have, then there probably</p> <p>19 should be more expert witness testimony.</p> <p>20 Perhaps I should be replaced by someone</p> <p>21 stronger.</p> <p>22 But if we have found that this FDA</p> <p>23 evidence will, in October, in front of a panel of</p> <p>24 federal judges, lead to the same conclusion, is there</p> <p>25 any value with my sitting there and coming up with the</p>	<p>1 That would be an even greater</p> <p>2 embarrassment.</p> <p>3 But at this point with what you're</p> <p>4 presenting me on the assumption that that FDA</p> <p>5 statement is backed by evidence and data, data that</p> <p>6 was generated by these inadequate systems, by</p> <p>7 voluntary reporting with an old drug, I believe a</p> <p>8 federal judge would discard my expert opinion in light</p> <p>9 of a stronger expert opinion.</p> <p>10 MR. KAPLAN: Thank you very much for</p> <p>11 your candor.</p> <p>12 THE WITNESS: That -- my -- what I want</p> <p>13 to make sure is my response is appropriate because I</p> <p>14 don't help anybody.</p> <p>15 MR. THOMPSON: Let's just wait until</p> <p>16 there's a question on the table. Okay?</p> <p>17 THE WITNESS: I'm sorry.</p> <p>18 BY MR. KAPLAN:</p> <p>19 Q. Go ahead. I didn't want to interrupt</p> <p>20 you. Go ahead.</p> <p>21 A. No. My main concern in taking this</p> <p>22 assignment was that I was adequately prepared by</p> <p>23 experience and seniority to be truly an expert</p> <p>24 witness. I did not realize the magnitude of the case.</p> <p>25 If you're going to start to do new work,</p>
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<p>1 same conclusion?</p> <p>2 I think the evidence issue is still</p> <p>3 open. But it appears that if we're making the</p> <p>4 assumptions that the FDA had all of this evidence and</p> <p>5 they will overrule this, this situation will probably</p> <p>6 repeat itself in October.</p> <p>7 And right now, I have to be very careful</p> <p>8 because I can't think of a way to rebut your</p> <p>9 presenting me with the FDA looked at this and came up</p> <p>10 with a different conclusion and they had the evidence</p> <p>11 you didn't have.</p> <p>12 I can't immediately contradict that.</p> <p>13 BY MR. KAPLAN:</p> <p>14 Q. Nor would you want to, would you?</p> <p>15 A. Not if it's foolish and untrue.</p> <p>16 Q. And you believe in the FDA? You believe</p> <p>17 they told the truth?</p> <p>18 They're telling the truth; right?</p> <p>19 A. Yes. I don't know whether there's</p> <p>20 potentially other information they did not have.</p> <p>21 I'd hate to be embarrassed by people --</p> <p>22 him replacing me with another expert witness and more</p> <p>23 evidence that shows that that FDA statement was not</p> <p>24 supported by all of this evidence that we don't now</p> <p>25 have that I haven't seen.</p>	<p>1 it is generally advisable to do it in a circumscribed</p> <p>2 setting where there is no question of one's adequacy</p> <p>3 for the magnitude of the litigation.</p> <p>4 If there's any question of that with me,</p> <p>5 I would have liked to have known it because I would</p> <p>6 not have proceeded.</p> <p>7 Now, that being said, I was asked to</p> <p>8 render opinion in a short time frame based on a given</p> <p>9 amount of evidence, and I asked for further evidence</p> <p>10 and I reviewed what was provided.</p> <p>11 I did not pull in some of the statements</p> <p>12 from the depositions. That was a deliberate</p> <p>13 statement, not to comment on the personnel in the</p> <p>14 depositions, but to stick with the evidence from the</p> <p>15 FDA.</p> <p>16 But at this point, I have been told I</p> <p>17 was adequate to do this job. The point to do it was</p> <p>18 to seek truth based on the evidence.</p> <p>19 And I had nothing to worry about with</p> <p>20 anybody accusing me of wrongdoing, either by going</p> <p>21 into something where I was not adequately prepared or</p> <p>22 -- or otherwise.</p> <p>23 So if you're presenting me with this</p> <p>24 evidence that the FDA had all of this evidence that I</p> <p>25 wanted, and there was no risk to public health, and</p>

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<p>1 the probability is that that would be confirmed by</p> <p>2 these federal judges on October 8th, then we have hit</p> <p>3 truth.</p> <p>4 We have hit an expert witness that is</p> <p>5 stronger than I am who has seen all of the data. We</p> <p>6 need to be sure they've seen all of the data.</p> <p>7 But for me to go in with the</p> <p>8 inexperience in expert witness, a report based on a</p> <p>9 sampling of data that may need to be modified and</p> <p>10 revisions may not serve anyone. And there may be --</p> <p>11 MR. THOMPSON: Doctor, you have said</p> <p>12 this many times.</p> <p>13 THE WITNESS: I'm sorry.</p> <p>14 MR. THOMPSON: I think we're -- I think</p> <p>15 we've got it.</p> <p>16 THE WITNESS: I'm more worried about me.</p> <p>17 And I wanted --</p> <p>18 MR. THOMPSON: That's a given.</p> <p>19 THE WITNESS: Yes.</p> <p>20 BY MR. KAPLAN:</p> <p>21 Q. You want to be vindicated. You want to</p> <p>22 go out with a --</p> <p>23 A. I want to be vindicated.</p> <p>24 Q. -- good feeling that you've arrived at</p> <p>25 the truth?</p>	<p>1 in this case. That -- I leave that up to you, really.</p> <p>2 MR. THOMPSON: Thank you.</p> <p>3 THE WITNESS: I don't -- I'm talking too</p> <p>4 much.</p> <p>5 MR. THOMPSON: Thank you.</p> <p>6 Dick, I think you've got some questions.</p> <p>7 BY MR. KAPLAN:</p> <p>8 Q. Well, if you have anything else that you</p> <p>9 want to say, anything, you know, this is your</p> <p>10 opportunity to go ahead and make any statements you</p> <p>11 want to make.</p> <p>12 A. Well, my concern in doing something new</p> <p>13 was to not -- I don't want to put the integrity of the</p> <p>14 litigation in jeopardy either way because of my</p> <p>15 inexperience.</p> <p>16 And so my going into a court as a</p> <p>17 lightweight does not serve these people. The question</p> <p>18 is, am I? But that's their decision.</p> <p>19 It's very clear right now that there's a</p> <p>20 certain -- that I am being entrained by whoever's</p> <p>21 questioning me.</p> <p>22 And my concern not to do anything wrong</p> <p>23 and vindicate myself, that may or may not be evidence</p> <p>24 of my inexperience with -- if I was a really heavy-</p> <p>25 weight expert witness, I might hit back. I'm not</p>
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<p>1 A. Yes. But these people offered me the</p> <p>2 opportunity to do something new and they trusted me to</p> <p>3 act on their behalf to really look at this. And under</p> <p>4 no way do I want to malign them or do them wrong.</p> <p>5 But what we're seeing is the process of</p> <p>6 discovery was more extensive than we realized. There</p> <p>7 may be more.</p> <p>8 But it looks like I was overruled by the</p> <p>9 FDA. And it would be foolish for me to go into a</p> <p>10 Federal Court and challenge that. There are people</p> <p>11 who do that.</p> <p>12 Q. But you're not one of them?</p> <p>13 A. I know attorneys who do that.</p> <p>14 Q. You're not one of them?</p> <p>15 A. It may be some day. But I think at this</p> <p>16 point in time, that I'm probably not the person to be</p> <p>17 doing that. That's my honest opinion.</p> <p>18 There are people that might be able to</p> <p>19 say to me tomorrow, Karen, we want you to do that.</p> <p>20 But I don't support the kind of litigation where</p> <p>21 people go in and challenge the FDA. I don't think I</p> <p>22 would have taken that.</p> <p>23 I know it's done. I know it's done</p> <p>24 successfully. And the people that do it, I agree with</p> <p>25 how they did it. I don't know that I should do that</p>	<p>1 ready right now to hit back.</p> <p>2 But I'm very concerned by the fact that</p> <p>3 you're showing me evidence the FDA looked at this and</p> <p>4 said there's no risk to public health and that there</p> <p>5 was a Congressional inquiry.</p> <p>6 So there was a -- this is already, you</p> <p>7 know, under a lot of scrutiny and has a high degree of</p> <p>8 certainty. I have to modify my opinion.</p> <p>9 MR. KAPLAN: Thank you very much.</p> <p>10 Thank you so much for your candor.</p> <p>11 EXAMINATION</p> <p>12 BY MR. DEAN:</p> <p>13 Q. I just have a few questions, but they're</p> <p>14 medical questions, they're factual questions. I want</p> <p>15 to -- I'd ask that you listen to the question. I</p> <p>16 think you'll be able to give short answers.</p> <p>17 They arise from a question that</p> <p>18 Mr. Thompson asked you or at least an answer that you</p> <p>19 gave to one of Mr. Thompson's questions.</p> <p>20 And that was about the information that</p> <p>21 went into gathering MedWatch reports in hard cases, in</p> <p>22 cases involving digitalis.</p> <p>23 So my question to you is this: Would</p> <p>24 you agree that people who are taking Digitek -- strike</p> <p>25 that.</p>

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<p>1 Would you agree that people who are not 2 taking Digitek, who have been prescribed it for an 3 underlying heart condition, that they can have higher 4 than normal levels with perfectly acceptable normal 5 tablets? 6 A. Yes. Digitalis toxicity is well 7 documented to occur with no concomitant abnormality in 8 the tablets. 9 Q. And it can occur for a variety of 10 medical reasons, such as renal failure, which develops 11 or gets worse than it was in the past; correct? 12 A. Yes. Intercurrent events, such as renal 13 failure, can precipitate digitalis toxicity. 14 Q. And a number of other medical events can 15 also lead to digitalis toxicity on perfectly normal 16 tablets; agreed? 17 A. Yes. 18 Q. And does -- and so what I was leading up 19 to, doesn't that make it extraordinarily difficult to 20 recognize through a safety signal analysis whether 21 there is a -- safety signal is throwing off or is 22 giving a signal of a defective tablet? 23 A. Yes. The statement from the consumer 24 group makes the point that -- I don't know whether we 25 should cite it verbatim, but it's very, very difficult</p>	<p>1 of those issues, even in conversations over lunch or 2 dinner, casual conversations. 3 I avoid, for the most part, commenting 4 on some of these high-profile cases. 5 I do know that some of these pro -- 6 high-profile cases that have used that argument have 7 been forced to settle. I cannot tell you -- 8 Q. Let me -- excuse me. 9 A. -- that I know -- 10 Q. I'm not asking you about other cases. 11 This is the only case involving Digitek that I'm aware 12 of. I don't know what other high-profile cases you're 13 talking about. 14 All of us would like to get out of here 15 in the not too distant future. My question was a very 16 focused question. 17 Are you aware of a recognized scientific 18 methodology by which a safety signal could be arrived 19 at to ascertain the defective Digitek was on the 20 market given the inherent difficulties we've spoken 21 about here in the last few minutes? 22 A. There is a -- boy, this is -- I have to 23 say this right. There is a significant possibility. 24 I was going to say high likelihood. I don't know how 25 to express this. But the lower the event rate, the</p>
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<p>1 to list causality to the Digitek tablets to any given 2 case. 3 And I made a note in the margin that at 4 this point I have no evidence to refute that 5 statement. 6 And I found when I looked up the drug 7 label, I told you I did go on the Internet, that it 8 confirmed that digitalis toxicity, clinical digitalis 9 toxicity, can be seen at normal -- normal therapeutic 10 levels. 11 So the person does not -- this is 12 extremely complicated. 13 However, one more thing, what I'm saying 14 right now is technically outside of the scope of my 15 review. 16 Q. Doesn't that make -- doesn't the fact, 17 though, that you just articulated from the consumer 18 group and the fact that you -- the facts that you've 19 testified to a few minutes ago that you can have high 20 levels with normal tablets, doesn't that make it 21 impossible to apply any recognized scientific 22 methodology to look at adverse events on Digitek and 23 conclude they were due to a tablet defect? 24 A. I know that this argument has been used 25 in prior litigation. I have specifically stayed out</p>	<p>1 harder it is to demonstrate. 2 For example, it's very difficult in 3 pesticides to show differences in cancer rates for 4 very, very low event rate cancers. 5 The lower the event rate, the harder it 6 is to find a vigorous scientific method to demonstrate 7 it and the larger the sample size you need to 8 demonstrate it. 9 It's -- there's increasing evidence that 10 this is a very, very low frequency event. But there's 11 a paucity of real hard evidence on what was the event 12 rate. That's where I started asking these questions. 13 The FDA has sort of confirmed that it's 14 a low event rate. Based on that, it becomes 15 increasingly difficult to scientifically demonstrate 16 in any given case. And that's what the consumer group 17 says. 18 And right now, I don't have the 19 information and I probably don't have the expertise to 20 refute that. You need somebody who carries a Ph.D. in 21 epidemiology. 22 Q. As we sit here today, you cannot cite to 23 me a recognized scientific methodology by which one 24 could discern a safety signal for defective Digitek 25 from looking at a set of medical records, can you?</p>

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<p>1 That's a very focused question. Can you</p> <p>2 cite me a recognized scientific methodology by which</p> <p>3 that can be done?</p> <p>4 A. I know the methodologies. I am not</p> <p>5 expert enough to render an opinion on their scientific</p> <p>6 validity for the low frequency events of the Digitek</p> <p>7 tablets.</p> <p>8 Q. Thank you.</p> <p>9 A. I know them generally for doing adverse</p> <p>10 event rates. I cannot comment on their implementation</p> <p>11 in this particular case.</p> <p>12 MR. DEAN: Thank you.</p> <p>13 I have no further questions.</p> <p>14 EXAMINATION</p> <p>15 BY MR. KAPLAN:</p> <p>16 Q. Would you be sad if we said we're at the</p> <p>17 conclusion of your deposition or would you be glad?</p> <p>18 A. Well, I would be glad.</p> <p>19 I do hope that if the Miller firm and</p> <p>20 Motley Rice feel that there is more evidence and they</p> <p>21 want to fight this FDA observation, that they will</p> <p>22 feel free to do it even if it's not wise to have me on</p> <p>23 the witness stand under questioning.</p> <p>24 I would hope that the fact that I have</p> <p>25 come to the point where I'd say this FDA press release</p>	<p>1 to be able to say whatever you want to say because</p> <p>2 this is your last opportunity to do so, maybe. It's</p> <p>3 your testimony under oath.</p> <p>4 So if there's any other statement you</p> <p>5 want to make or any concern you want to express --</p> <p>6 A. I want assurance that my insecurity</p> <p>7 because I'm new to this expert witness game has not</p> <p>8 led me to abandon an opinion and fail my client.</p> <p>9 But I have difficulty arguing with that</p> <p>10 statement of the FDA, if it's based on the data that I</p> <p>11 wanted to see, because I'm afraid there are other</p> <p>12 people that would weigh the FDA more than me.</p> <p>13 Q. I just want you to understand this.</p> <p>14 This is not an expert witness game.</p> <p>15 A. Oh, I know this.</p> <p>16 Q. It's not a game. This is a real-life,</p> <p>17 serious situation in which plaintiffs are asking for</p> <p>18 millions of dollars, millions and millions of dollars,</p> <p>19 from our clients.</p> <p>20 They're accusing our clients of</p> <p>21 wrongdoing. We're doing our best to defend our</p> <p>22 clients.</p> <p>23 You understand that?</p> <p>24 A. I understand the implications. And I've</p> <p>25 used words about myself that may or may not be</p>
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<p>1 and the fact that they probably have the documentation</p> <p>2 that I didn't have might negate any further analysis</p> <p>3 by me negligible.</p> <p>4 If there are people who can get that</p> <p>5 evidence and continue this, where it may not be wise</p> <p>6 for me to do it, under no circumstances do I want my</p> <p>7 present testimony to inhibit their further pursuit of</p> <p>8 truth if there is evidence that the FDA opinion should</p> <p>9 be contradicted.</p> <p>10 Right now, I have not been presented</p> <p>11 any. But I do want to go on record that these people</p> <p>12 hired me, and I'm in a very difficult situation right</p> <p>13 now.</p> <p>14 And under no circumstances do I want to</p> <p>15 undermine their position if they want to continue this</p> <p>16 course of litigation.</p> <p>17 I think it -- I'm pretty comfortable</p> <p>18 with where I've had to come based on what I've</p> <p>19 presented, and I guess --</p> <p>20 MR. THOMPSON: Okay.</p> <p>21 THE WITNESS: -- I have to stop talking.</p> <p>22 MR. DEAN: Let's go off the record.</p> <p>23 We're finished.</p> <p>24 BY MR. KAPLAN:</p> <p>25 Q. You don't have to. I mean, I want you</p>	<p>1 appropriate descriptors.</p> <p>2 This is a very big case, and I expressed</p> <p>3 concern from the outset that my role, particularly as</p> <p>4 things started to be disclosed that this was more than</p> <p>5 I had originally agreed to do, would not jeopardize</p> <p>6 the correct outcome of the case.</p> <p>7 There is a chance that there's -- my</p> <p>8 insecurity with my inexperience at this that's causing</p> <p>9 the problem. And I don't want to hurt anybody.</p> <p>10 I want this to actually -- people said</p> <p>11 just seek to come to truth. And that's what they're</p> <p>12 asking you to do.</p> <p>13 Q. And that's what you've done today to the</p> <p>14 best of your ability, to seek the truth, to seek to</p> <p>15 testify to the truth; correct?</p> <p>16 A. I believe that. I do have some fears</p> <p>17 that there could be people who would want to fight the</p> <p>18 FDA. I know there's people who do this.</p> <p>19 And there's a chance that that's what</p> <p>20 this case will evolve into. But at this point, you've</p> <p>21 presented me with a witness that I believe overrules</p> <p>22 me.</p> <p>23 MR. DEAN: Thank you.</p> <p>24 MR. KAPLAN: All right. Thank you.</p> <p>25 MR. DEAN: Let's go off the record.</p>

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1 VIDEO OPERATOR: Any more questions?
2 MR. DEAN: No more questions.
3 VIDEO OPERATOR: We are now going off
4 the video record.
5 This is the end of Tape 6 and concludes
6 the videotaped deposition of Karen A. Frank, M.D., on
7 June 30th, 2010.
8 The time is 5:39 p.m.
9 (Witness excused.)
10 (The deposition concluded at 5:39 p.m.)
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1 WITNESS CERTIFICATION
2
3
4
5 I hereby certify that I have read
6 the foregoing transcript of my deposition testimony,
7 and that my answers to the questions propounded, with
8 the attached corrections or changes, if any, are true
9 and correct.
10
11
12
13
14
15 DATE KAREN A. FRANK, M.D.
16
17
18
19 PRINTED NAME
20
21
22
23
24
25

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ability 220:12	accidentally 69:14	185:22,23 187:12	96:8	135:20 137:7
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